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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL : MDL NO. 2804
PRESCRIPTION OPIATE :
LITIGATION :

: CASE NO.
THIS DOCUMENT : 1:17-MD-2804
RELATES TO ALL CASES:
: Hon. Dan A.
: Polster

- - -

Friday, January 18, 2019

- - -

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Videotaped deposition of
CAROL MARCHIONE, taken pursuant to
notice, was held at Golkow Litigation
Services, One Liberty Place, 1650 Market
Street, Suite 5150, Philadelphia,
Pennsylvania 19103, beginning at 9:31
a.m., on the above date, before Amanda
Dee Maslynsky-Miller, a Certified
Realtime Reporter.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

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<p style="text-align: right;">Page 2</p> <p>1 APPEARANCES:</p> <p>2 SKIKOS, CRAWFORD, SKIKOS & JOSEPH, LLP</p> <p>3 BY: MARK G. CRAWFORD, ESQUIRE</p> <p>4 BY: DYLAN JENSEN, ESQUIRE</p> <p>5 One Sansome Street</p> <p>6 Suite 2830</p> <p>7 San Francisco, California 94104</p> <p>(415) 546-7300</p> <p>8 Mcrawford@skikos.com</p> <p>Djensen@skikos.com</p> <p>9 Representing the Plaintiffs</p> <p>10 BRANSTETTER, STRANCH & JENNINGS,</p> <p>11 PLLC</p> <p>12 BY: BENJAMIN A. GASTEL, ESQUIRE</p> <p>13 223 Rosa L. Parks Avenue</p> <p>Suite 200</p> <p>Nashville, Tennessee 37203</p> <p>(877) 369-0267</p> <p>Beng@bsjfirm.com</p> <p>14 Representing the Staubus Plaintiffs</p> <p>15 MORGAN, LEWIS & BOCKIUS LLP</p> <p>16 BY: TINOS DIAMANTATOS, ESQUIRE</p> <p>77 West Wacker Drive</p> <p>17 Chicago, Illinois 60601</p> <p>(312) 324-1484</p> <p>Tinos.diamantatos@morganlewis.com</p> <p>- and -</p> <p>21 BY: VINEETA PRAKASH KAMATH, ESQUIRE</p> <p>1111 Pennsylvania Avenue NW</p> <p>22 Washington, DC 20004</p> <p>(202) 739-3000</p> <p>23 Representing the Defendant,</p> <p>Teva Corporation</p>	<p style="text-align: right;">Page 4</p> <p>1 APPEARANCES: (Continued)</p> <p>2 VIA TELEPHONE/LIVESTREAM:</p> <p>3 REED SMITH, LLP</p> <p>4 BY: RYAN K. BLAKE, ESQUIRE</p> <p>5 Three Logan Square</p> <p>1717 Arch Street, Suite 3100</p> <p>6 Philadelphia, Pennsylvania, 19103</p> <p>(215) 851-8100</p> <p>7 Rblake@reedsmit.com</p> <p>8 Representing the Defendant,</p> <p>AmerisourceBergen</p> <p>11 ALLEGERT BERGER & VOGEL LLP</p> <p>BY: LAUREN J. PINCUS, ESQUIRE</p> <p>12 111 Broadway, 20th Floor</p> <p>New York, New York 10006</p> <p>(212) 616-7075</p> <p>Lpinicus@abv.com</p> <p>14 Representing the Defendant,</p> <p>Rochester Drug Corporation</p> <p>17 ALSO PRESENT:</p> <p>David Lane, Videographer</p> <p>Rich Christian, Trial Technician</p>
<p style="text-align: right;">Page 3</p> <p>1 APPEARANCES: (Continued)</p> <p>2 JONES DAY</p> <p>3 BY: SHUBHA M. HARRIS, ESQUIRE</p> <p>4 90 South Seventh Street</p> <p>Suite 4950</p> <p>5 Minneapolis, MN 55402</p> <p>(612) 217-8800</p> <p>6 Shubhaharris@jonesday.com</p> <p>Representing the Defendant,</p> <p>7 Walmart</p> <p>10 PIETRAGALLO GORDON ALFANO BOSICK &</p> <p>RASPANTI</p> <p>11 BY: LESLIE A. MARIOTTI, ESQUIRE</p> <p>12 1818 Market Street</p> <p>Suite 3402</p> <p>13 Philadelphia, Pennsylvania 19103</p> <p>(215) 320-6200</p> <p>14 LAM@pietragallo.com</p> <p>Representing the Defendant,</p> <p>15 Cardinal Health, Inc.</p> <p>18 ARNOLD & PORTER KAYE SCHOLER LLP</p> <p>BY: WILSON D. MUDGE, ESQUIRE</p> <p>601 Massachusetts Ave, NW</p> <p>Washington, DC 20001</p> <p>(202) 942-5000</p> <p>20 Wilson.mudge@arnoldporter.com</p> <p>Representing the Defendant,</p> <p>21 Endo Pharmaceuticals, Endo Health,</p> <p>and Par Pharmaceuticals</p>	<p style="text-align: right;">Page 5</p> <p>1 - - -</p> <p>2 I N D E X</p> <p>3 - - -</p> <p>4 Testimony of: CAROL MARCHIONE</p> <p>5 By Mr. Crawford 11, 537</p> <p>6 By Mr. Diamantatos 511</p> <p>7 By Mr. Gastel 499</p> <p>8 - - -</p> <p>9 E X H I B I T S</p> <p>10 - - -</p> <p>11 NO. DESCRIPTION PAGE</p> <p>12 Teva-Marchione</p> <p>13 Exhibit-1 Resume, Carol S. Marchione 14</p> <p>14 Teva-Marchione</p> <p>15 Exhibit-2 LinkedIn, Carol S.</p> <p>16 Marchione 43</p> <p>17 Teva-Marchione</p> <p>18 Exhibit-3 TEVA_MDL_A_01861562-572 45</p> <p>19 Teva-Marchione</p> <p>20 Exhibit-4 Org Chart, Regulatory</p> <p>Affairs, 2004 45</p> <p>21 Teva-Marchione</p> <p>22 Exhibit-5 TEVA_MDL_A_08242688-693 68</p> <p>23 Teva-Marchione</p> <p>24 Exhibit-6 No Bates</p> <p>1998 21 CFR 314.520 79</p> <p>Teva-Marchione</p> <p>Exhibit-7 TEVA_MDL_A_03272088-117 83</p>

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7	Exhibit-9 TEVA_MDL_A_04578988-9017 130	Exhibit-32 TEVA_MDL_A_02074924-969 426
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<p>1 - - -</p> <p>2 (It is hereby stipulated and 3 agreed by and among counsel that 4 sealing, filing and certification 5 are waived; and that all 6 objections, except as to the form 7 of the question, will be reserved 8 until the time of trial.) 9 - - -</p> <p>10 VIDEO TECHNICIAN: We are 11 now on the record. My name is 12 David Lane, videographer for 13 Golkow Litigation Services. 14 Today's date is January 18th, 15 2019. Our time is 9:31 a.m. 16 This deposition is taking 17 place in Philadelphia, 18 Pennsylvania, in the matter of 19 National Prescription Opiate 20 Litigation MDL. Our deponent 21 today is Carol Marchione. Counsel 22 will be noted on the stenographic 23 record. The court reporter is 24 Amanda Miller, who will now swear</p>	<p>1 Q. And have you ever had your 2 deposition taken before? 3 A. Yes, I have. 4 Q. And about how many times? 5 A. At least twice. 6 Q. And what were those cases 7 about? 8 A. One was for Actiq, a 9 fentanyl product for dental decay. And 10 to be honest, I can't remember what the 11 other one was for. 12 Q. What was the nature of the 13 Actiq lawsuit? 14 Was it a lawsuit? 15 A. I believe it was, yes. 16 Q. And do you know what the 17 claims were in that suit? 18 A. The claims were that Actiq 19 caused significant tooth loss, due to the 20 sugar in the product. 21 Q. And how long ago was that 22 deposition? 23 A. God. I can approximate, ten 24 years ago.</p>
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<p>1 in our witness. 2 - - -</p> <p>3 CAROL MARCHIONE, after 4 having been duly sworn, was 5 examined and testified as follows: 6 - - -</p> <p>7 VIDEO TECHNICIAN: Please 8 begin. 9 - - -</p> <p>10 EXAMINATION 11 - - -</p> <p>12 BY MR. CRAWFORD: 13 Q. Good morning. 14 A. Good morning. 15 Q. My name is Mark Crawford, I 16 represent the plaintiffs in the opioid 17 litigation. 18 Can you please state your 19 name? 20 A. Sure. Carol Marchione. 21 Q. And where is your current 22 home and work addresses? 23 A. They're both the same. And 24 it's [REDACTED]</p>	<p>1 Q. Okay. So you know -- you're 2 aware you're under oath right now, 3 correct? 4 A. Yes, I am, I'm aware. 5 Q. And the deposition is being 6 videotaped? 7 A. Yes, I am. 8 Q. And I guess the basic rules, 9 you know to make audible responses, not 10 nodding your head or -- yes or no. 11 A. I understand. 12 Q. And if you don't understand 13 a question, please ask me to rephrase it. 14 A. I will do that. 15 Q. And take any breaks when you 16 need them. 17 A. Okay. Thank you. 18 Q. All right. And you're aware 19 that your testimony here could be used at 20 trial before a jury, correct? 21 A. That's my understanding. 22 Q. And if your counsel had 23 asked you if you would appear at a trial 24 in this case, would you be ready and</p>

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<p style="text-align: right;">Page 14</p> <p>1 willing to go to trial to testify? 2 A. I believe so. 3 Q. And you're represented here 4 by counsel? 5 A. I am. 6 Q. But you're not a current 7 Teva employee, are you? 8 A. I am not. 9 Q. And what's your current work 10 position or occupation? 11 A. I have my own consulting 12 business. So I'm a principal of 13 Marchione and Associates, LLC. 14 Q. And what does your business 15 do? 16 A. Regulatory affairs 17 consulting for pharmaceutical companies. 18 Q. And is Teva or Cephalon any 19 of your current clients? 20 A. No, they are not. 21 Q. How about Actavis? 22 A. No, they're not. 23 Q. All right. 24 - - -</p>	<p style="text-align: right;">Page 16</p> <p>1 lists RiskMAPs and promotion review, 2 right? 3 A. Correct. 4 Q. And what is a RiskMAP? 5 A. A RiskMAP is the predecessor 6 to what the FDA calls a REMS. So it was 7 a program that was put into place with 8 the FDA to control or -- distribution and 9 sales of products that they have safety 10 concerns. And it's associated with 11 Subpart H, approved products, such as 12 Actiq and Fentora. 13 Q. And what is Subpart H? 14 A. Subpart H is a section under 15 21 C.F.R. 314 which discusses marketing 16 approval of pharmaceutical drugs. 17 Q. And, you know, what is the 18 purpose or intent of Subpart H? 19 A. Subpart H is for -- to 20 accelerate approval of life-threatening 21 drugs. That's the intention. 22 However, usually any drug 23 that they have a concern of safety, 24 they've invoked Subpart H to be able to</p>
<p style="text-align: right;">Page 15</p> <p>1 (Whereupon, Teva-Marchione 2 Exhibit-1, Resume, Carol S. 3 Marchione, was marked for 4 identification.) 5 - - - 6 BY MR. CRAWFORD: 7 Q. We've marked as Exhibit-1 8 Document 560. But as Exhibit-1, it is 9 a -- appears to be a resume. 10 Is this your resume? 11 A. It's an old resume. 12 Q. Right, okay. And it 13 summarizes your experience here. 14 Is this -- maybe take a 15 quick look at it. 16 Does this accurately reflect 17 your work history up to this point, and 18 qualifications? 19 A. Yes, it does. 20 Q. And you provide a summary of 21 your experience up at the top. About 22 midway through, it says, Experience 23 includes success with wide variety of FDA 24 regulated mechanisms, such as -- and it</p>	<p style="text-align: right;">Page 17</p> <p>1 control more tightly for -- for 2 postmarketing. 3 Q. So is it kind of conditions 4 or requirements placed on the company 5 with regard to the drug, to make sure 6 that it is safely used? 7 MR. DIAMANTATOS: Objection 8 to form. 9 Go ahead. 10 BY MR. CRAWFORD: 11 Q. Would that be a fair 12 characterization? 13 MR. DIAMANTATOS: Objection 14 to form. 15 THE WITNESS: Generally, 16 yes. 17 BY MR. CRAWFORD: 18 Q. And did Actiq and Fentora 19 have RiskMAPs? 20 A. Actiq had a RiskMAP. And 21 I'm thinking that -- I told you that was 22 the predecessor of REMS. 23 Fentora, I think, was under 24 a REMS. So it was an evolution, but the</p>

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<p>1 same principles applied.</p> <p>2 Q. All right. And it says,</p> <p>3 under -- your first positions you list</p> <p>4 here were Teva Pharmaceuticals, formerly</p> <p>5 Cephalon, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And you were there from 2000</p> <p>8 until about November 2011, right?</p> <p>9 A. No. I was --</p> <p>10 Q. Until present, yeah.</p> <p>11 So when did you leave Teva?</p> <p>12 A. It was 2013,</p> <p>13 approximately -- I think it was May,</p> <p>14 around 2013.</p> <p>15 Q. All right. And it says one</p> <p>16 of the accomplishments was successfully</p> <p>17 negotiated multiple product approvals.</p> <p>18 And you list Fentora and</p> <p>19 Actiq, correct?</p> <p>20 A. That's correct.</p> <p>21 Q. And are those two drugs, you</p> <p>22 mentioned that they were under a RiskMAP</p> <p>23 or a REMS, right?</p> <p>24 A. Correct.</p>	<p>1 THE WITNESS: I don't</p> <p>2 remember exactly. But, again,</p> <p>3 RiskMAP preceded REMS. So I don't</p> <p>4 know when Congress agreed, or if</p> <p>5 they agreed. I'm just dealing</p> <p>6 with the FDA, in terms of their</p> <p>7 guidances.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Is it your understanding</p> <p>10 that the RiskMAP -- let me strike that.</p> <p>11 Is it your understanding</p> <p>12 that the REMS was a process that the FDA</p> <p>13 was given power to impose conditions or</p> <p>14 these plans onto drugs that have already</p> <p>15 been approved, when, before they had that</p> <p>16 power, they couldn't -- they couldn't</p> <p>17 unilaterally do that?</p> <p>18 MR. DIAMANTATOS: Objection.</p> <p>19 Form. Foundation.</p> <p>20 Go ahead.</p> <p>21 THE WITNESS: So they had</p> <p>22 the approval when they approved</p> <p>23 Subpart H, which was back in --</p> <p>24 before that. I think it evolved</p>
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<p>1 Q. And RiskMAP, what is --</p> <p>2 that's kind of an acronym.</p> <p>3 What does that stand for, do</p> <p>4 you know?</p> <p>5 A. It's obsolete now, so -- I</p> <p>6 think it was risk -- I don't know what</p> <p>7 the "map" stands for now. I just can't</p> <p>8 remember the exact acronym, what it</p> <p>9 meant.</p> <p>10 Q. How about REMS, what does</p> <p>11 that acronym stand for?</p> <p>12 A. Risk evaluation and</p> <p>13 mitigation processes or plans --</p> <p>14 Q. Strategy?</p> <p>15 A. -- strategy plans.</p> <p>16 Q. Okay. So risk evaluation</p> <p>17 and mitigation strategy?</p> <p>18 A. That's correct.</p> <p>19 Q. All right. And REMS was</p> <p>20 something that Congress instituted,</p> <p>21 correct me if I'm wrong, in about 2007 or</p> <p>22 '08, right?</p> <p>23 MR. DIAMANTATOS: Objection</p> <p>24 to form. Foundation.</p>	<p>1 since then.</p> <p>2 So they had the power in the</p> <p>3 Act to do that, and the law</p> <p>4 prior -- when the RiskMAP was in</p> <p>5 place.</p> <p>6 So it evolved, then, the</p> <p>7 FDA, my understanding, interpreted</p> <p>8 the guidances and they did -- I</p> <p>9 understand they got more direction</p> <p>10 from the Congress from there.</p> <p>11 But it started with the</p> <p>12 Subpart H approval.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. So let me just try to</p> <p>15 clarify at least the regulatory</p> <p>16 standpoint.</p> <p>17 A. Sure.</p> <p>18 Q. It's my understanding, and</p> <p>19 let me see if it's also your</p> <p>20 understanding, that for RiskMAPs, which</p> <p>21 preceded the REMS programs, RiskMAPs</p> <p>22 could be imposed with regard -- in</p> <p>23 conjunction with the approval of a</p> <p>24 pharmaceutical drug, right?</p>

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<p>1 A. Correct.</p> <p>2 Q. But it couldn't be imposed</p> <p>3 by the FDA after the approval, I guess,</p> <p>4 unless it was agreed to by the</p> <p>5 manufacturer, right?</p> <p>6 MR. DIAMANTATOS: Objection</p> <p>7 to form. Foundation.</p> <p>8 Go ahead.</p> <p>9 THE WITNESS: That's my</p> <p>10 understanding.</p> <p>11 BY MR. CRAWFORD:</p> <p>12 Q. And then after the REMS</p> <p>13 program was put in place, the FDA was</p> <p>14 given the power to impose that type of</p> <p>15 risk strategy on a drug that was already</p> <p>16 approved without getting the agreement of</p> <p>17 the manufacturer, right?</p> <p>18 MR. DIAMANTATOS: Object to</p> <p>19 form. Foundation.</p> <p>20 THE WITNESS: Again, I'm</p> <p>21 aware of the -- what was in the</p> <p>22 law in the RiskMAP. I can't be</p> <p>23 specific about when -- the REMS</p> <p>24 and how that was associated with</p>	<p>1 approved indication for Actiq?</p> <p>2 A. Actiq was approved for</p> <p>3 breakthrough -- cancer breakthrough pain</p> <p>4 in opioid-tolerant patients, for</p> <p>5 breakthrough, yes, breakthrough pain.</p> <p>6 Q. So it was breakthrough pain?</p> <p>7 A. Yes.</p> <p>8 Q. Was Actiq also approved only</p> <p>9 for use by cancer patients?</p> <p>10 A. Yes.</p> <p>11 Q. And tell me what</p> <p>12 breakthrough pain is.</p> <p>13 A. So breakthrough pain are the</p> <p>14 spikes of intense pain that occur in a --</p> <p>15 over time.</p> <p>16 Q. And Actiq was intended to</p> <p>17 treat this breakthrough pain in cancer</p> <p>18 patients, right?</p> <p>19 A. That's correct.</p> <p>20 Q. Was -- when Actiq was</p> <p>21 approved, was it approved to be used in</p> <p>22 noncancer patients?</p> <p>23 A. No.</p> <p>24 Q. So you had to have cancer,</p>
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<p>1 the law.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. But your understanding was,</p> <p>4 with REMS, the FDA can impose a REMS</p> <p>5 without the consent of the manufacturer?</p> <p>6 A. Yes, that's correct.</p> <p>7 Q. All right. So Actiq and</p> <p>8 Fentora, those are two drugs.</p> <p>9 What period of time was</p> <p>10 Actiq marketed by Cephalon?</p> <p>11 A. I'd say approximately 2001,</p> <p>12 until Fentora got approved, which was, I</p> <p>13 don't know, 2010, something around there.</p> <p>14 Q. Would 2006 make sense?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. And then Fentora was</p> <p>17 approved in 2006, right?</p> <p>18 A. Okay, yes.</p> <p>19 Q. And it was a drug, by the</p> <p>20 time you left in 2013, it was still being</p> <p>21 marketed by Cephalon, right?</p> <p>22 A. I don't -- I believe so.</p> <p>23 Q. And can you tell me what</p> <p>24 Actiq was indicated for? What was the</p>	<p>1 really -- well, that was -- the approved</p> <p>2 indication was for cancer patients' use</p> <p>3 only, right?</p> <p>4 A. That's correct.</p> <p>5 MR. DIAMANTATOS: Objection</p> <p>6 to form.</p> <p>7 Go ahead.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. And can you kind of describe</p> <p>10 what the product looked like?</p> <p>11 MR. DIAMANTATOS: Objection</p> <p>12 to form.</p> <p>13 THE WITNESS: It was a</p> <p>14 lozenge on a handle, with a tag at</p> <p>15 the bottom of the handle.</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. And you would stick it in</p> <p>18 your mouth kind of like a lollipop?</p> <p>19 A. That's correct.</p> <p>20 Q. And then it would dissolve</p> <p>21 quickly in the mouth and give you a shot</p> <p>22 of what, of fentanyl, correct?</p> <p>23 A. That's correct.</p> <p>24 Q. And that would alleviate the</p>

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<p style="text-align: right;">Page 26</p> <p>1 pain, the breakthrough pain, right? That 2 was the intent of the product?</p> <p>3 A. That's the intention, yes.</p> <p>4 Q. And when Fentora was 5 approved -- that was 2006, we decided, 6 right?</p> <p>7 A. Yes, I believe so.</p> <p>8 Q. And was that -- at the time, 9 do you know if Actiq had had -- the 10 patent had expired for Actiq in 2006?</p> <p>11 Do you know if that's the 12 case?</p> <p>13 A. I just don't remember.</p> <p>14 Q. But Fentora was meant to be 15 kind of a replacement drug, by Cephalon, 16 for Actiq, right?</p> <p>17 MR. DIAMANTATOS: Objection 18 to form. Foundation.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. In the market.</p> <p>21 MR. DIAMANTATOS: Same 22 objections.</p> <p>23 THE WITNESS: That's my 24 understanding.</p>	<p style="text-align: right;">Page 28</p> <p>1 THE WITNESS: I'm not a 2 physician. But it's respiratory 3 distress, I understand.</p> <p>4 BY MR. CRAWFORD:</p> <p>5 Q. So -- and how did -- can you 6 explain the mechanism of how Fentora 7 operated?</p> <p>8 MR. DIAMANTATOS: Objection. 9 Foundation.</p> <p>10 THE WITNESS: Can you 11 explain that question better?</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. Yes.</p> <p>14 Actiq was a dissolving 15 lozenge at the end of a stick.</p> <p>16 How was Fentora structured?</p> <p>17 A. It was a buccal lozenge that 18 you put in your mouth and it 19 disintegrated. So it was similar in 20 process.</p> <p>21 Q. It just didn't have a stick 22 on it, right?</p> <p>23 A. I think there was a 24 different PK profile, but I don't</p>
<p style="text-align: right;">Page 27</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. And Fentora has, basically, 3 an identical indication as Actiq, right?</p> <p>4 A. That's what I remember.</p> <p>5 Q. And that was only for use in 6 cancer patients and for breakthrough 7 pain, right?</p> <p>8 MR. DIAMANTATOS: Objection 9 to form.</p> <p>10 THE WITNESS: In 11 opioid-tolerant, yes, patients.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. And what do you mean by 14 "opioid-tolerant patients"?</p> <p>15 A. Patients who have had -- 16 been exposed previously to opioids and 17 had enough buildup to be tolerant, so 18 they wouldn't -- so there was no lethal 19 adverse events.</p> <p>20 Q. So what were the dangers of 21 somebody who wasn't opioid tolerant using 22 the drug?</p> <p>23 MR. DIAMANTATOS: Objection. 24 Foundation.</p>	<p style="text-align: right;">Page 29</p> <p>1 remember.</p> <p>2 Q. "PK" stands for?</p> <p>3 A. Pharmacokinetic.</p> <p>4 Q. So you started at Cephalon 5 in 2000 as director of regulatory 6 affairs.</p> <p>7 What were, generally, your 8 responsibilities as director of 9 regulatory affairs from 2000 until 10 December of 2001?</p> <p>11 A. I was responsible for the 12 interactions with the Food and Drug 13 Administration for both oncology and -- 14 at that point, the only pain product was 15 Actiq.</p> <p>16 Q. And then you were promoted, 17 is that a promotion, to senior director 18 of regulatory affairs from 2002 to 2006, 19 correct?</p> <p>20 A. That's correct.</p> <p>21 Q. And did your 22 responsibilities change, or were there 23 additional ones?</p> <p>24 A. I don't remember. I'm</p>

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<p>1 sure -- you know, I'm sure something 2 changed, but I don't remember. 3 Q. But you still had 4 responsibilities for Actiq, correct? 5 A. I did. 6 Q. And what were your 7 responsibilities with regard to Actiq as 8 senior director of regulatory affairs? 9 A. Overseeing submissions to 10 FDA and all communication between the FDA 11 and the company, and to sit on 12 development and commercial teams 13 representing the regulations, the U.S. 14 regulations.</p> <p>15 Q. And did you have any 16 responsibilities with regard to the Actiq 17 RiskMAP?</p> <p>18 A. I did.</p> <p>19 Q. And what were those, that 20 you recall?</p> <p>21 A. I was -- there was an annual 22 report -- I'm sorry, there was a 23 quarterly compilation of information to 24 be sent to FDA, and oversight for --</p>	<p>1 to form. 2 THE WITNESS: We would send 3 out a request document, who was -- 4 the people who were responsible 5 throughout the company, to ask 6 them for information, which they 7 would send and we would compile 8 and review.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. All right. And then -- what 11 departments, generally, would you get 12 information from?</p> <p>13 MR. DIAMANTATOS: Objection 14 to form.</p> <p>15 THE WITNESS: Medical 16 affairs; commercial; safety; maybe 17 manufacturing, I think; and 18 quality.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. And "commercial" means the 21 sales and marketing department?</p> <p>22 A. That's correct.</p> <p>23 Q. So you depend on the 24 accuracy of information that those</p>
Page 31	Page 33
<p>1 regulatory oversight for that -- for the 2 RiskMAP.</p> <p>3 Q. And would you help prepare 4 that report for the FDA on a quarterly 5 basis, you said?</p> <p>6 A. Initially. And then I had a 7 subordinate that I hired to do that.</p> <p>8 Q. And who was that?</p> <p>9 A. Tracie Parker.</p> <p>10 Q. But you maintained overall 11 responsibility for that report?</p> <p>12 MR. DIAMANTATOS: Objection 13 to form.</p> <p>14 Go ahead.</p> <p>15 THE WITNESS: I did.</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. So you would review the 18 reports that went to the FDA after Ms. 19 Parker prepared them?</p> <p>20 A. That's correct.</p> <p>21 Q. And how was information 22 collected or gathered for that report 23 during these time periods?</p> <p>24 MR. DIAMANTATOS: Objection</p>	<p>1 departments provided to you in submitting 2 your report, right?</p> <p>3 MR. DIAMANTATOS: Objection. 4 Form.</p> <p>5 THE WITNESS: That's 6 correct.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. So would you do anything -- 9 if sales and marketing gave you 10 information to put in the report, would 11 you do anything to verify its accuracy, 12 or would you accept the information your 13 colleagues are providing as being 14 accurate?</p> <p>15 MR. DIAMANTATOS: Objection. 16 Form.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. What was your practice?</p> <p>19 A. Right. Quality assurance 20 had the responsibility to check the 21 processes. So I accepted what was 22 received.</p> <p>23 Q. And quality assurance, that 24 was a department at Cephalon?</p>

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1	A. That's correct.	1 Form. Foundation.
2	Q. And they would periodically	2 Go ahead.
3	perform audits of these departments to	3 THE WITNESS: Yes, I guess.
4	make sure the RiskMAP was properly	4 I don't know.
5	implemented?	5 BY MR. CRAWFORD:
6	MR. DIAMANTATOS: Objection.	6 Q. Do you know if Actiq was
7	Form and foundation.	7 being actively marketed, or had they
8	THE WITNESS: That was their	8 stopped actively marketing it after they
9	responsibility. I can't say how	9 brought on Fentora?
10	they did it or when they did it or	10 MR. DIAMANTATOS: Objection.
11	how.	11 Form.
12	BY MR. CRAWFORD:	12 THE WITNESS: That's not my
13	Q. And what -- it's your	13 area. I believe -- I believe that
14	understanding that it was their	14 was the case, but I can't say for
15	responsibility during the period that	15 sure.
16	Aktiq, at least, was being marketed?	16 BY MR. CRAWFORD:
17	MR. DIAMANTATOS: Objection.	17 Q. Right. Thank you.
18	Form. Foundation.	18 And then you were promoted,
19	THE WITNESS: That was my	19 senior director, head of oncology, global
20	understanding. I can't ascertain	20 regulatory affairs.
21	what exactly happened.	21 That was a promotion, or
22	BY MR. CRAWFORD:	22 just a lateral move?
23	Q. So then you were promoted, a	23 A. It was lateral. Because at
24	promotion, I assume, to senior director	24 that point, I believe the pain area went
	Page 35	Page 37
1	and group leader, regulatory affairs,	1 over to somebody else. So I was then
2	from '07 to October 2011, correct?	2 just oncology.
3	A. Correct.	3 Q. Right. Did you have any
4	Q. And what was -- did your	4 responsibilities for Actiq or Fentora
5	responsibilities change in that position?	5 from November 2011 forward?
6	A. I can't remember.	6 A. There was a period of time
7	Q. And this would have been the	7 when they asked me to take over during an
8	period when Fentora was being actively	8 interim -- I think when the vice
9	marketed by the company, right?	9 president left or whatever.
10	MR. DIAMANTATOS: Objection.	10 But for the most part, I was
11	Form.	11 oncology at that point.
12	Go ahead.	12 Q. And that doesn't involve the
13	THE WITNESS: So Fentora was	13 pain drugs?
14	approved in 2006. I can't tell	14 A. That's correct.
15	you exactly, you know, when -- I	15 Q. And so you didn't have,
16	don't know what month it was	16 unless -- except for this interim period,
17	approved, but I can assume.	17 you didn't have responsibility for Actiq
18	BY MR. CRAWFORD:	18 and Fentora?
19	Q. All right. So if it was	19 A. That's correct.
20	approved in '06, during the 2007 to 2011	20 Q. And then you left --
21	period, that's the period that Fentora	21 MR. CRAWFORD: Did we get
22	was being actively marketed by the	22 that other document?
23	company, right?	23 MR. JENSEN: No, not yet.
24	MR. DIAMANTATOS: Objection.	24 BY MR. CRAWFORD:

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<p>1 Q. We have a LinkedIn page, 2 we're waiting for a hardcopy, but can we 3 throw that up, and maybe mark it later as 4 Exhibit-2.</p> <p>5 MR. DIAMANTATOS: Sure. 6 MR. CRAWFORD: All right. 7 Let's put up Document 556. 8 BY MR. CRAWFORD: 9 Q. I just want to round out 10 your work history, so we pulled that 11 page.</p> <p>12 MR. MUDGE: Excuse me, this 13 is Will Mudge, for Endo and Par. 14 Do these documents you're showing 15 have Bates numbers on them, or are 16 they not numbered?</p> <p>17 MR. CRAWFORD: The resume 18 was numbered, so I would be happy 19 to read it into the record. The 20 LinkedIn is --</p> <p>21 MR. MUDGE: That one, I 22 think, is okay. But just if any 23 of these do have a Bates number, 24 if you could read them, that would</p>	<p>1 could be off. 2 BY MR. CRAWFORD: 3 Q. All right. 4 A. But, in general, that's 5 correct. 6 Q. Thank you for that 7 clarification. 8 So you left Teva -- is it 9 accurate that you left Teva about April 10 of 2013? 11 A. That's correct. 12 Q. And what were the 13 circumstances of your leaving Teva? 14 A. Teva, which is how I 15 pronounce it, stopped oncology 16 development. And I decided to go consult 17 on my own, because oncology is my 18 strength area. So I wanted to continue 19 doing regulatory for that. 20 Q. After you left Teva, did you 21 do any work in pain medications? 22 MR. DIAMANTATOS: Objection. 23 Form. 24 THE WITNESS: One of my</p>
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<p>1 be very helpful to me. 2 MR. CRAWFORD: Sure. I 3 would be happy to do that. 4 BY MR. CRAWFORD: 5 Q. So we're going to mark, in a 6 second, this document as Exhibit-2, but 7 we have it up on the screen. 8 This seems to round out your 9 work history, correct?</p> <p>10 MR. DIAMANTATOS: Objection 11 to form. 12 BY MR. CRAWFORD: 13 Q. At least after Teva? 14 A. It appears correct. 15 Q. So the information is 16 accurate on this?</p> <p>17 MR. DIAMANTATOS: Objection 18 to the form. Asked and answered. 19 THE WITNESS: I can't 100 20 percent -- there's actually -- I 21 checked LinkedIn pretty recently. 22 My current C.V. matches correctly, 23 but I know there's another 24 LinkedIn timeline, so the months</p>	<p>1 clients was in the pain area. 2 BY MR. CRAWFORD: 3 Q. And what client was that? 4 A. I'm hesitating because I 5 think there's a confidentiality clause. 6 I don't know if I can relay that. 7 Q. Well, let's discuss that at 8 a break. So that's fine. Thank you for 9 that. 10 So you left and you went to 11 Creative Regulatory Solutions for 12 pharmaceutical development and 13 commercialization; is that -- 14 A. That's incorrect. 15 Q. Okay. 16 A. The name of my company is 17 Marchione and Associates, LLC. 18 So that's not my title. 19 That's not my company. 20 Q. All right. So you became a 21 principal managing director of your own 22 company, at least, from May of 2013 to 23 December 2014, right? 24 A. I believe that's the -- let</p>

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<p style="text-align: right;">Page 42</p> <p>1 me see.</p> <p>2 Q. Or thereabouts. I won't</p> <p>3 hold you to the exact month.</p> <p>4 A. Approximately, yes.</p> <p>5 Q. And then you -- it looks</p> <p>6 like you moved back into business with</p> <p>7 TetraLogic Pharmaceuticals from about</p> <p>8 January of 2015 until some time in early</p> <p>9 2016; is that correct?</p> <p>10 A. I believe so.</p> <p>11 Q. And what particular products</p> <p>12 were you involved with there?</p> <p>13 A. Oncology.</p> <p>14 Q. And then you left them again</p> <p>15 for Inipcoll Pharmaceuticals, from May</p> <p>16 of 2016 to about January of 2017; is that</p> <p>17 correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And what types of drugs did</p> <p>20 you deal with there?</p> <p>21 MR. DIAMANTATOS: Objection</p> <p>22 to form.</p> <p>23 Go ahead.</p> <p>24 THE WITNESS: That was a</p>	<p style="text-align: right;">Page 44</p> <p>1 2000; it looks like Aventis, Ligand, U.S.</p> <p>2 BioScience and RW Johnson Research; is</p> <p>3 that -- back to '91.</p> <p>4 Were all of those in</p> <p>5 regulatory positions with those</p> <p>6 companies?</p> <p>7 MR. DIAMANTATOS: Objection</p> <p>8 to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. And did you handle any</p> <p>12 matters dealing with pain products there</p> <p>13 at any of these companies?</p> <p>14 MR. DIAMANTATOS: Objection</p> <p>15 to form.</p> <p>16 THE WITNESS: At McNeil, I</p> <p>17 worked on the topiramate, which is</p> <p>18 Topamax, and Tramadol</p> <p>19 applications. I think topiramate</p> <p>20 has a pain indication. But</p> <p>21 Tramadol is definitely pain.</p> <p>22 BY MR. CRAWFORD:</p> <p>23 Q. And you have a degree,</p> <p>24 Bachelor of Science in biology in 1998 --</p>
<p style="text-align: right;">Page 43</p> <p>1 pain product for surgery.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. And was it an opioid</p> <p>4 product?</p> <p>5 A. No.</p> <p>6 Q. And then from January 2018</p> <p>7 to the present, you're now principal in</p> <p>8 your own consulting company that you</p> <p>9 referenced earlier, right?</p> <p>10 A. That's correct.</p> <p>11 Q. So we do have the hardcopy,</p> <p>12 we just marked it Exhibit-2.</p> <p>13 - - -</p> <p>14 (Whereupon, Teva-Marchione</p> <p>15 Exhibit-2, LinkedIn, Carol S.</p> <p>16 Marchione, was marked for</p> <p>17 identification.)</p> <p>18 - - -</p> <p>19 THE WITNESS: Thank you.</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. And going back to your</p> <p>22 resume, it looks like prior to joining</p> <p>23 Teva, you had been at various</p> <p>24 pharmaceutical companies prior to July</p>	<p style="text-align: right;">Page 45</p> <p>1 1980, from Villanova, correct?</p> <p>2 A. That's correct.</p> <p>3 Q. And any other degrees or</p> <p>4 graduate degrees?</p> <p>5 A. No.</p> <p>6 Q. All right. Let's move on</p> <p>7 here.</p> <p>8 MR. CRAWFORD: Actually, I'm</p> <p>9 going to mark the next document.</p> <p>10 This will be Document 1554, and</p> <p>11 also 548. These are a couple of</p> <p>12 organizational charts. And I will</p> <p>13 read the Bates number into the</p> <p>14 record.</p> <p>15 Exhibit-3 is Bates</p> <p>16 TEVA_MDL_A_01861572, and Exhibit-4</p> <p>17 is TEVA_MDL_A_01373072.</p> <p>18 - - -</p> <p>19 (Whereupon, Teva-Marchione</p> <p>20 Exhibit-3,</p> <p>21 TEVA_MDL_A_01861562-572, was</p> <p>22 marked for identification.)</p> <p>23 - - -</p> <p>24 (Whereupon, Teva-Marchione</p>

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1	Exhibit-4, Org Chart, Regulatory	1 sorry. Exhibit-3 is the one that
2	Affairs, 2004, was marked for	2 has the regulatory affairs on the
3	identification.)	3 last page of Bates 1572.
4	- - -	4 MR. CRAWFORD: Okay. We can
5	BY MR. CRAWFORD:	5 go with that.
6	Q. So these are -- Exhibit-3	6 MR. DIAMANTATOS: And the
7	appears to be a corporate org chart for	7 witness also has Exhibit-4, which
8	regulatory affairs, dated May 28th, 2003,	8 is the one-page document which
9	in the bottom left.	9 ends in 3072.
10	And then what appears to be	10 MR. CRAWFORD: Okay.
11	a different configuration in an org chart	11 MR. DIAMANTATOS: Sorry to
12	dated June 28th, 2004.	12 interrupt. I just wanted to make
13	Do these charts reflect, to	13 sure the record was clear.
14	your recollection, the organization of	14 MR. CRAWFORD: No, that's
15	the regulatory affairs departments during	15 good. Thank you. Let's go with
16	these time periods?	16 that. I must have had something
17	MR. DIAMANTATOS: Counsel,	17 different in my files.
18	excuse me. I don't know that we	18 BY MR. CRAWFORD:
19	have the right exhibits on the	19 Q. So we have Exhibit-3, a
20	right Bates, at least I'm not	20 chart, starting with TEVA_MDL_A_01861562,
21	tracking which ones you're looking	21 clinical research and regulatory affairs.
22	at.	22 If you go to the last page,
23	MR. CRAWFORD: Okay.	23 that appears to be the tree where you're
24	MR. DIAMANTATOS: So I have	24 located, correct?
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1	what's been handed to me, and has	1 A. Correct.
2	also been handed to the witness,	2 Q. And that is dated May 28th,
3	Exhibit-4 is a one-page document,	3 2003.
4	the Bates ends in 3072.	4 And then Exhibit-4 is the
5	MR. CRAWFORD: Okay.	5 one dated June 28th, 2004, that's
6	MR. DIAMANTATOS: And I've	6 TEVA_MDL_A_01373072.
7	also been handed, as has the	7 And I just wanted to ask if
8	witness, a document which has been	8 this, to your recollection, accurately
9	labeled Exhibit-3, it's a	9 reflects how your departments -- your
10	multipage document.	10 department was organized within the
11	MR. CRAWFORD: I may have	11 corporate hierarchy or structure during
12	pulled a page out of Exhibit-3.	12 these times?
13	So is there a regulatory affairs	13 MR. DIAMANTATOS: Objection
14	page ending in 72?	14 to form.
15	THE WITNESS: The last page.	15 Go ahead.
16	MR. DIAMANTATOS: The last	16 THE WITNESS: Yes.
17	page of the document ends in Bates	17 BY MR. CRAWFORD:
18	72.	18 Q. And let's start with '03.
19	MR. CRAWFORD: Okay. That	19 So you're listed here as a
20	will be Exhibit -- that's	20 senior director of regulatory affairs.
21	Exhibit-3?	21 And you had underneath you, or working
22	MR. JENSEN: 4.	22 for you, Tracie Parker and Susan
23	MR. CRAWFORD: 4, okay.	23 Williamson, correct?
24	MR. DIAMANTATOS: No, I'm	24 A. Yes.

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<p>1 Q. All right. And they were -- 2 were their functions mostly to help you 3 manage the regulatory affairs department? 4 A. They may have had 5 responsibility for specific drugs, and I 6 oversaw their capabilities.</p> <p>7 Q. All right. Good. Thank 8 you.</p> <p>9 And then it looks like the 10 position above you is vacant, vice 11 president of worldwide regulatory 12 affairs.</p> <p>13 Who was your superior there 14 when you joined the company?</p> <p>15 MR. DIAMANTATOS: Objection. 16 Form.</p> <p>17 THE WITNESS: Oh, God. I 18 can't remember his name.</p> <p>19 I'm sorry, I just don't 20 remember his name right now.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. That's fine. It was quite a 23 while ago.</p> <p>24 But do you remember there</p>	<p>1 in the department until you left for the 2 oncology wing?</p> <p>3 MR. DIAMANTATOS: Objection 4 to form.</p> <p>5 THE WITNESS: Yeah, I would 6 need exact dates, because there 7 were -- I had multiple managers. 8 So I would need the exact date.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Why don't you just walk me 11 through the chronology of managers? 12 So you had Mr. Raczkowski, 13 right?</p> <p>14 MR. DIAMANTATOS: Objection. 15 Form.</p> <p>16 Go ahead.</p> <p>17 THE WITNESS: Well, 18 initially I had Ken White.</p> <p>19 There was a vacancy where I 20 reported to the chief medical 21 officer temporarily.</p> <p>22 BY MR. CRAWFORD:</p> <p>23 Q. Who was that?</p> <p>24 A. It was originally Paul</p>
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<p>1 being a vacancy in that position above 2 you?</p> <p>3 A. Yes. I remember -- it was 4 Ken, Ken White. Yes.</p> <p>5 And Ken White left 6 approximately a year or two after I 7 started. So yes.</p> <p>8 Q. And how long did that 9 position stay vacant during this period?</p> <p>10 A. You know, I really don't 11 remember.</p> <p>12 Q. And it looks like it was 13 eventually filled by Victor Raczkowski; 14 is that correct?</p> <p>15 A. That's correct.</p> <p>16 Q. If you look at Exhibit-4. 17 So you reported to Mr. 18 Raczkowski after -- when he filled that 19 position starting at least in 2004, 20 right?</p> <p>21 A. That's correct.</p> <p>22 Q. And can you walk me through 23 your various -- I mean, was he your 24 superior during the entire time you were</p>	<p>1 Blake, and then I think he put Leslie 2 Russel underneath him.</p> <p>3 And then Victor Raczkowski 4 was there for a couple of years. And 5 then he left and I had -- what was his 6 name -- Eric Floyd for about two years, 7 and he left.</p> <p>8 And then I had Jim Ottinger 9 by the time I left.</p> <p>10 Q. How do you spell Ottinger?</p> <p>11 A. O-T-T-I-N-G-E-R.</p> <p>12 Q. And where were -- where was 13 Mr. Raczkowski based? Was he in your 14 office?</p> <p>15 MR. DIAMANTATOS: Objection. 16 Form.</p> <p>17 THE WITNESS: Yes, he was in 18 Malvern at the time.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. And that's where you were 21 located, Malvern?</p> <p>22 A. That's correct.</p> <p>23 Q. And were you in Malvern the 24 entire time you were there at Cephalon</p>

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<p>1 and Teva?</p> <p>2 A. No.</p> <p>3 Q. Give me what offices you</p> <p>4 were in and when you switched.</p> <p>5 A. Initially when I started in</p> <p>6 2000, the office was in West Chester.</p> <p>7 And then we moved offices across the</p> <p>8 street for a year, or whatever.</p> <p>9 And then we moved to</p> <p>10 Malvern. And that's pretty much the</p> <p>11 whole time I was there, from that point</p> <p>12 on.</p> <p>13 Q. So your superiors were</p> <p>14 always in the same office you were?</p> <p>15 MR. DIAMANTATOS: Objection</p> <p>16 to form.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. Except for the interim</p> <p>19 period, maybe?</p> <p>20 A. That's correct.</p> <p>21 Q. And looking at Exhibit-4, it</p> <p>22 looks like you still have Tracie Parker</p> <p>23 underneath you. And then you now have</p> <p>24 Penny Levin, Ruth Kearns and Darren</p>	<p>1 at some point by Teva, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And that was around 2011?</p> <p>4 A. I believe so.</p> <p>5 Q. And remind me, is that about</p> <p>6 the time that you switched to oncology,</p> <p>7 right, 2011?</p> <p>8 If you look at Exhibit-1,</p> <p>9 that might refresh your recollection.</p> <p>10 A. You showed me the -- yes.</p> <p>11 Thank you.</p> <p>12 2007 is when I became head</p> <p>13 of oncology.</p> <p>14 Q. Oh, okay. No. I don't</p> <p>15 think that's accurate here.</p> <p>16 I think it was November 2011</p> <p>17 you became head of oncology, right?</p> <p>18 A. No.</p> <p>19 Q. Okay. So you were senior</p> <p>20 director and group leader, regulatory</p> <p>21 affairs, from 2007 to 2011, right?</p> <p>22 A. I was senior director and</p> <p>23 group leader, it says -- let me get my</p> <p>24 glasses -- 2007 to 2011, that's correct.</p>
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<p>1 Dorman below you.</p> <p>2 Did they -- were those three</p> <p>3 added after the -- May of 2003 to your</p> <p>4 department?</p> <p>5 A. I believe so.</p> <p>6 Q. And did they assist you with</p> <p>7 various products in the regulatory</p> <p>8 aspect?</p> <p>9 A. Yes.</p> <p>10 MR. DIAMANTATOS: Objection</p> <p>11 to form.</p> <p>12 Go ahead.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. And during this period, you</p> <p>16 had responsibility for Actiq, right?</p> <p>17 MR. DIAMANTATOS: Objection.</p> <p>18 Form.</p> <p>19 THE WITNESS: That is</p> <p>20 correct.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. All right. That's all I had</p> <p>23 on those.</p> <p>24 Now, Cephalon was acquired</p>	<p>1 Q. And so then you moved to</p> <p>2 head of oncology in November 2011, right?</p> <p>3 A. That's correct. Sorry.</p> <p>4 Q. And do you know who</p> <p>5 succeeded you in the position --</p> <p>6 regulatory affairs position that oversaw</p> <p>7 Fentora?</p> <p>8 A. I don't remember. Maybe</p> <p>9 Penny Levin may have taken that</p> <p>10 responsibility. I just don't remember.</p> <p>11 Q. Do you remember when --</p> <p>12 after the acquisition, was there a</p> <p>13 counterpart regulatory person at Teva</p> <p>14 that you interacted with?</p> <p>15 MR. DIAMANTATOS: Objection</p> <p>16 to form.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: For,</p> <p>19 specifically, you mean, as a</p> <p>20 manager?</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. That was a bad question. So</p> <p>23 I'll withdraw it.</p> <p>24 I'm trying to find out, so</p>

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<p>1 when Teva took over, there was -- 2 obviously, was there any kind of merger 3 of operations at all with Teva USA and 4 Cephalon?</p> <p>5 MR. DIAMANTATOS: Objection 6 to form.</p> <p>7 THE WITNESS: No, not 8 really. There was -- there could 9 have been some reorganization. I 10 just don't remember.</p> <p>11 Things went back-and-forth 12 numerous times, so that's why it's 13 difficult for me to remember when 14 and who and exactly --</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Right. Did Teva bring in 17 any of their regulatory people into your 18 department at all after the acquisition?</p> <p>19 A. Yes.</p> <p>20 Q. Do you remember who that 21 was?</p> <p>22 A. Mike -- what was Mike's last 23 name? He came from Teva and he reported 24 to me. What's Mike's last name?</p>	<p>1 Go ahead. 2 THE WITNESS: I believe when 3 they merged, I think Jim Ottinger, 4 who was head of branded products, 5 became head of at least branded, 6 and then eventually I think he 7 took over generic also.</p> <p>8 BY MR. CRAWFORD: 9 Q. And was he already with 10 Teva -- 11 A. No. He was hired -- I don't 12 know exactly what year, but he was hired 13 in.</p> <p>14 Q. After the merger?</p> <p>15 MR. DIAMANTATOS: Objection. 16 Form. Foundation.</p> <p>17 THE WITNESS: I'm not 18 exactly sure which -- the date or 19 when that was.</p> <p>20 BY MR. CRAWFORD: 21 Q. And after Teva acquired 22 Cephalon, did you become an employee of 23 Teva, or did you stay an employee of 24 Cephalon?</p>
<p>1 And, yes, there were 2 different people that were brought in.</p> <p>3 Q. And when Teva purchased 4 Cephalon, did Teva have its own opioid 5 products, pain products?</p> <p>6 MR. DIAMANTATOS: Objection 7 to form. Foundation.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Generic?</p> <p>10 MR. DIAMANTATOS: Objection 11 to form. Foundation.</p> <p>12 THE WITNESS: I don't -- I 13 don't know. I didn't interact 14 with the generic group. I can't 15 tell you.</p> <p>16 The generic group was 17 separate when I was there.</p> <p>18 BY MR. CRAWFORD:</p> <p>19 Q. Do you know who was head of 20 regulatory or in the regulatory 21 department for Teva after you guys 22 joined?</p> <p>23 MR. DIAMANTATOS: Objection. 24 Form. Foundation.</p>	<p>1 A. An employee of Teva. 2 Q. And what Teva entity 3 employed you? Do you know the name? 4 A. Teva Pharmaceuticals. 5 Q. What was the full name? 6 Teva Pharmaceuticals USA, or do you know? 7 A. I think it was just Teva 8 Pharmaceuticals. 9 Q. All right. Do you recall 10 what your compensation was at the time 11 you left Teva? 12 A. I'd approximate it to be 13 about 270 a year. 14 Q. And about what was it when 15 you started? 16 A. All the way back in 2000? I 17 don't know. I'd approximate it at 125. 18 Q. And did you receive bonuses 19 or stock options as part of your 20 compensation? 21 A. Yes. 22 Q. And was that on a yearly 23 basis while you were there? 24 A. Generally.</p>
	16 (Pages 58 to 61)

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<p>1 Q. And what were those bonuses 2 based on? Your bonuses and your stock 3 options, what were they based on? 4 MR. DIAMANTATOS: Objection 5 to form. 6 BY MR. CRAWFORD: 7 Q. What type of performance? 8 MR. DIAMANTATOS: Objection 9 to form. 10 THE WITNESS: I believe 11 that -- 12 MR. CRAWFORD: Strike that. 13 BY MR. CRAWFORD: 14 Q. Were they performance-based, 15 the bonuses and stock options? 16 A. Yes. 17 Q. And what were the criteria 18 for determining how much you would get? 19 MR. DIAMANTATOS: Objection. 20 Form. Foundation. Time frame. 21 THE WITNESS: So it differed 22 by time frame. 23 BY MR. CRAWFORD: 24 Q. Just walk me through from</p>	<p>1 A. Every year there were 2 objectives, and if you met the 3 objectives. 4 Q. And then the company 5 performance, what was that based on? Its 6 revenues or profits? Was that any of the 7 criteria? 8 MR. DIAMANTATOS: Objection. 9 Form. Foundation. 10 THE WITNESS: Company 11 objectives -- there was company 12 objectives, department objectives, 13 and then my personal objectives. 14 BY MR. CRAWFORD: 15 Q. So that was your 16 understanding of what your bonus and 17 stock option awards were based on? 18 A. That's correct. 19 Q. And would this have been the 20 entire time period you were there, or did 21 it change? 22 A. That's my recollection. 23 Q. And then when you left the 24 company, we did take a look at your</p>
Page 63	Page 65
<p>1 when you started until you left Teva, 2 what you can remember, as far as the 3 criteria. 4 MR. DIAMANTATOS: Objection. 5 Form. 6 THE WITNESS: I think when I 7 began, my initial level, it could 8 have been a bonus was maybe 25 9 percent of my salary. And I think 10 it went up -- this was the 11 target -- it was approximately 32 12 percent. 13 But that was based upon not 14 just my performance, the 15 department performance and then 16 the company performance. So there 17 was an algorithm. 18 BY MR. CRAWFORD: 19 Q. And how was your department 20 performance measured? 21 MR. DIAMANTATOS: Objection. 22 Form. Foundation. 23 BY MR. CRAWFORD: 24 Q. If you know.</p>	<p>1 personnel file, and it looked like you 2 had gotten a \$50,000 bonus in February 3 2012; an \$87,000 in March of 2013; a 4 \$260,000 payment in May of 2013; and even 5 after you left, we saw a \$29,000 pay 6 stub. 7 Are these amounts that seem 8 in line with what your recollection is? 9 MR. DIAMANTATOS: Objection. 10 Form. 11 THE WITNESS: It sounds 12 about right. 13 BY MR. CRAWFORD: 14 Q. And so the \$260,000 payment 15 in May of 2013, was that considered a 16 severance-type of payment? Or what was 17 the basis of that payment? 18 MR. DIAMANTATOS: Objection. 19 Form. 20 THE WITNESS: That was a 21 severance. 22 BY MR. CRAWFORD: 23 Q. And then the \$87,000 bonus 24 in March of 2013, what was that based on?</p>

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<p style="text-align: right;">Page 66</p> <p>1 A. That was the annual bonus. 2 Q. And the \$50,000 bonus in 3 February 2012, that, again, was the 4 annual bonus? 5 A. That's correct. 6 Q. And in addition to these 7 cash bonuses, you could get -- or you did 8 get stock options, too, correct? 9 A. That's correct. 10 Q. And approximately -- is 11 there any way to quantify the stock 12 options you received towards the end 13 there? 14 MR. DIAMANTATOS: Objection. 15 Form. 16 THE WITNESS: I really don't 17 remember -- 18 BY MR. CRAWFORD: 19 Q. Number of shares or value? 20 A. -- because there were grant 21 options. It's so complex, I couldn't 22 understand it from year to year. So I 23 can't remember it right now. Sorry. 24 Q. Do you currently own Teva</p>	<p style="text-align: right;">Page 68</p> <p>1 BY MR. CRAWFORD: 2 Q. And now do you own any 3 Cephalon or Teva stock? 4 MR. DIAMANTATOS: Objection. 5 Form. Asked and answered. 6 THE WITNESS: No, I do not. 7 MR. CRAWFORD: Let's pull up 8 Document 596 and mark the next 9 exhibit. 10 - - - 11 (Whereupon, Teva-Marchione 12 Exhibit-5, 13 TEVA_MDL_A_08242688-693, was 14 marked for identification.) 15 - - - 16 BY MR. CRAWFORD: 17 Q. So what we've marked here as 18 Exhibit-5 is a -- it looks like it's 19 stamped November 4th, 1998 letter from 20 the Department of Health and Human 21 Services to Anesta Corporation. And it's 22 document TEVA_MDL_A_08242688. 23 And this appears to be the 24 approval letter for Actiq.</p>
<p style="text-align: right;">Page 67</p> <p>1 stock? 2 A. No, I do not. 3 Q. And it was granted in Teva 4 stock, right? 5 MR. DIAMANTATOS: Objection. 6 Form. 7 THE WITNESS: It depends 8 what year you're talking about. 9 BY MR. CRAWFORD: 10 Q. So before Teva acquired 11 Cephalon, was it Cephalon stock that you 12 were given options? 13 MR. DIAMANTATOS: Objection. 14 Form. Assumes facts. 15 THE WITNESS: Yes. 16 BY MR. CRAWFORD: 17 Q. Yes? 18 A. Yes. 19 Q. And then after Teva acquired 20 Cephalon, were the stock options for Teva 21 stock? 22 MR. DIAMANTATOS: Objection. 23 Form. 24 THE WITNESS: I believe so.</p>	<p style="text-align: right;">Page 69</p> <p>1 Is that what this looks like 2 to you? 3 A. Give me one second. 4 MR. DIAMANTATOS: Objection. 5 Foundation. 6 THE WITNESS: That's my 7 understanding. 8 BY MR. CRAWFORD: 9 Q. And Anesta Corporation was 10 purchased by Cephalon some time before 11 you arrived at Cephalon, correct? 12 A. That's correct. 13 Q. And Patricia Richards, was 14 she at all in your department or at your 15 company when you joined Cephalon? 16 A. No. 17 Q. So this letter, go down to 18 the third paragraph. It says, This new 19 drug application provides for the use of 20 Actiq for the management of breakthrough 21 cancer pain in patients with malignancies 22 who are already receiving and who are 23 tolerant to opioid therapy for their 24 underlying persistent cancer pain.</p>

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<p style="text-align: right;">Page 70</p> <p>1 Is that your understanding 2 of what the approval -- the indication 3 was for Actiq that was approved by the 4 FDA? 5 A. In general. Sometimes the 6 actual labeled indication is slightly 7 different. 8 Q. All right. But you do 9 understand that it was approved only for 10 patients who had cancer, malignancies, 11 correct? 12 MR. DIAMANTATOS: Objection 13 to form. 14 THE WITNESS: That's what it 15 says here, yes. 16 BY MR. CRAWFORD: 17 Q. Right. But that's your 18 understanding of, ultimately, what it was 19 approved for, or at least one of the 20 conditions, right? 21 MR. DIAMANTATOS: Objection 22 to form. Asked and answered. 23 THE WITNESS: Yes. 24 BY MR. CRAWFORD:</p>	<p style="text-align: right;">Page 72</p> <p>1 the time -- in the FDA's view that the 2 risk management program was essential to 3 be implemented for the safe use of the 4 product? 5 MR. DIAMANTATOS: Objection 6 to the form. Foundation. Calls 7 for speculation. 8 THE WITNESS: So you're 9 asking me for the FDA's view. And 10 what you just asked me is written 11 clearly here, so I'm assuming that 12 that's the case. 13 BY MR. CRAWFORD: 14 Q. But you understood that in 15 order for Actiq to be a safe drug, it 16 needed to be marketed in accordance with 17 the RiskMAP? 18 MR. DIAMANTATOS: Objection. 19 Form. Foundation. 20 THE WITNESS: That wasn't 21 necessarily my determination. But 22 what I'm understanding is that the 23 FDA has deemed that. 24 BY MR. CRAWFORD:</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. It then says, in the next 2 paragraph, We have reviewed this 3 application under the restricted 4 distribution regulations contained in 21 5 C.F.R. 314.520, Subpart H, and have 6 concluded that restrictions on 7 distribution and use of Actiq are needed 8 to assure safe use of the product. 9 So this was the Subpart H 10 you were referring to, correct? 11 A. Yes. 12 Q. And then they state that, We 13 have completed the review of this 14 application, including the Actiq risk 15 management program, RMP, as amended. We 16 have concluded that adequate information 17 has now been presented to demonstrate 18 that Actiq is safe and effective when 19 marketed in accordance with the terms of 20 restricted distribution and use described 21 in the risk management program. 22 So is it your understanding 23 that, in order for, in the FDA's view -- 24 and this is just how you understood at</p>	<p style="text-align: right;">Page 73</p> <p>1 Q. All right. Thank you. 2 And then if you can go to 3 the next page, referencing changes to the 4 Actiq risk management program, it says, 5 Please note the attached risk management 6 program, RMP, is an integral part of the 7 approved NDA for this product and is an 8 essential component of the terms of this 9 NDA's approval by the FDA for marketing 10 this product in the United States. As 11 such, any proposed changes in the risk 12 management program must be submitted to 13 FDA as a supplement to the NDA, and any 14 proposed change must have FDA prior 15 approval before implementation. Changing 16 the risk management program without prior 17 FDA approval may render the product 18 misbranded and an unapproved new drug. 19 So reading that, does that 20 refresh any recollection that if the 21 RiskMAP was going to be changed by the 22 company, you needed FDA approval first 23 before implementing those changes? 24 MR. DIAMANTATOS: Objection.</p>

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<p style="text-align: right;">Page 74</p> <p>1 Form. Foundation.</p> <p>2 THE WITNESS: There was</p> <p>3 significant communication with the</p> <p>4 FDA. We tried many, many times,</p> <p>5 over the course of years, to</p> <p>6 revise the RiskMAP, and they would</p> <p>7 not provide us feedback. We</p> <p>8 submitted supplements, they never</p> <p>9 answered it.</p> <p>10 So it got to the point there</p> <p>11 were administrative issues that we</p> <p>12 had to change. So I communicated.</p> <p>13 I wrote to them. I finally said</p> <p>14 that we need to change -- not</p> <p>15 we're not changing any fundamental</p> <p>16 issues, but because of the</p> <p>17 administration issues that we have</p> <p>18 to acknowledge, we were changing</p> <p>19 and please let us know as soon as</p> <p>20 possible.</p> <p>21 And you'll find that in the</p> <p>22 documentation.</p> <p>23 BY MR. CRAWFORD:</p> <p>24 Q. Did they ultimately ever</p>	<p style="text-align: right;">Page 76</p> <p>1 And so from that point on,</p> <p>2 when I submitted a quarterly that</p> <p>3 had a change, let's say, it went</p> <p>4 to -- you know, Walmart to</p> <p>5 Walgreens or something like that,</p> <p>6 I had to say, this is a change and</p> <p>7 we're acknowledging it's</p> <p>8 administrative, but it's not</p> <p>9 substantively changing the</p> <p>10 RiskMAP.</p> <p>11 And we had to do it that way</p> <p>12 because we couldn't get</p> <p>13 communication back.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. But you agree, at least in</p> <p>16 the beginning, the FDA is saying, in</p> <p>17 order to get a change or before</p> <p>18 implementing it, you have to get our</p> <p>19 prior approval, right?</p> <p>20 MR. DIAMANTATOS: Objection.</p> <p>21 Form. Foundation. Calls for</p> <p>22 speculation. Asked and answered.</p> <p>23 THE WITNESS: That's what it</p> <p>24 says here.</p>
<p style="text-align: right;">Page 75</p> <p>1 approve any supplements for any changes</p> <p>2 in the Actiq RiskMAP?</p> <p>3 MR. DIAMANTATOS: Objection.</p> <p>4 Form. Vague. Foundation.</p> <p>5 THE WITNESS: I don't</p> <p>6 believe they ever did, to be</p> <p>7 honest.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Was there one change -- and</p> <p>10 I just remember looking through the</p> <p>11 records -- where I think you submit some</p> <p>12 type of supplement changing the name of</p> <p>13 the sales force or something that</p> <p>14 detailed the drug?</p> <p>15 MR. DIAMANTATOS: Objection.</p> <p>16 Form.</p> <p>17 THE WITNESS: I know I did</p> <p>18 at least one. And then it got to</p> <p>19 be, again, multiple</p> <p>20 communications, e-mails. I'd have</p> <p>21 to estimate ten to fifteen</p> <p>22 communications were done where</p> <p>23 they would not respond to the</p> <p>24 changes we requested.</p>	<p style="text-align: right;">Page 77</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. Do you know why the FDA was</p> <p>3 not acting on any proposed changes that</p> <p>4 you say were being made or asked --</p> <p>5 requested?</p> <p>6 MR. DIAMANTATOS: Objection.</p> <p>7 Form. Calls for speculation.</p> <p>8 Foundation.</p> <p>9 THE WITNESS: No, I do not.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. If you could turn to Page</p> <p>12 692 at the bottom.</p> <p>13 A. Got you.</p> <p>14 Q. They are stating here, the</p> <p>15 FDA, in the letter to Anesta, In</p> <p>16 addition, please note that this product</p> <p>17 is only -- has been approved only for the</p> <p>18 management of breakthrough cancer pain in</p> <p>19 patients with malignancies who are</p> <p>20 already receiving and who are tolerant to</p> <p>21 opioid therapy for their underlying</p> <p>22 persistent cancer pain. As such, please</p> <p>23 note the promotional statements or</p> <p>24 representations by you that this product</p>

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<p style="text-align: right;">Page 78</p> <p>1 may, indeed, be safe and efficacious in 2 the treatment of diseases or patient 3 populations beyond that contained in your 4 approved labeling may be considered a 5 violation of the Act.</p> <p>6 So does that comport, as a 7 person, as somebody with regulatory 8 background, with what the rules are with 9 regard to promoting a product, an 10 FDA-approved product?</p> <p>11 MR. DIAMANTATOS: Objection. 12 Form.</p> <p>13 Go ahead.</p> <p>14 THE WITNESS: Yes.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. And when you joined Cephalon 17 in the regulatory department, would it 18 have been your practice to go back and 19 look at the initial approval files of the 20 drug that you -- drugs that you were 21 working with?</p> <p>22 A. If something required it, 23 yes.</p> <p>24 Q. Do you believe that you may</p>	<p style="text-align: right;">Page 80</p> <p>1 Exhibit-5, the approval letter, right? 2 A. I believe so, yes. 3 Q. And is that Subpart H right 4 here, or at least part of it? 5 A. It's part of it. 6 Q. And I tried to pull the 7 version back in 1998. I don't know if 8 it's changed. 9 But it does say, If the FDA 10 concludes that a drug product shown to be 11 effective can be safely used only if 12 distribution or use is restricted, FDA 13 will require such postmarketing 14 restrictions as needed to assure safe use 15 of the drug product. 16 So is that your 17 understanding of what Subpart H and the 18 FDA is requiring when they approved 19 Actiq? 20 MR. DIAMANTATOS: Objection 21 to form. 22 THE WITNESS: They invoked 23 that subsection of Subpart H when 24 they approved Actiq.</p>
<p style="text-align: right;">Page 79</p> <p>1 have reviewed this letter at any time? 2 A. Yes. 3 Q. And do you believe you would 4 have reviewed it early in your tenure 5 there at Cephalon?</p> <p>6 MR. DIAMANTATOS: Objection 7 to form. 8 Go ahead.</p> <p>9 THE WITNESS: Yes.</p> <p>10 MR. CRAWFORD: All right. 11 Let's go to the next document 12 here.</p> <p>13 MR. JENSEN: Exhibit-6. 14 MR. CRAWFORD: This doesn't 15 have a Bates number.</p> <p>16 - - - 17 (Whereupon, Teva-Marchione 18 Exhibit-6, No Bates, 1998 21 CFR 19 314.520, was marked for 20 identification.)</p> <p>21 - - - 22 BY MR. CRAWFORD: 23 Q. I pulled 314.520, which that 24 was the section referenced on Page 1 of</p>	<p style="text-align: right;">Page 81</p> <p>1 BY MR. CRAWFORD: 2 Q. Right. So the FDA there was 3 requiring the RiskMAP to assure that the 4 drug would be safely used, Actiq, right? 5 MR. DIAMANTATOS: Objection. 6 Form. Foundation. 7 BY MR. CRAWFORD: 8 Q. Under Subpart H, in your 9 understanding? 10 MR. DIAMANTATOS: Objection. 11 Form. Foundation. Calls for 12 speculation. 13 THE WITNESS: I'm sorry, can 14 you repeat the first part of that 15 question? 16 BY MR. CRAWFORD: 17 Q. We got kind of interchanged 18 there. I'd be happy to do that. 19 I'm just -- now that you've 20 seen the letter and you've seen, 21 actually, the text of Subpart H that at 22 least we pulled here, is it your 23 understanding that the FDA -- that a drug 24 approved under Subpart H imposes</p>

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<p>1 conditions to ensure that the drug that 2 is approved under that section would be 3 used safely?</p> <p>4 MR. DIAMANTATOS: Objection. 5 Form.</p> <p>6 THE WITNESS: That it would 7 be restricted to -- I'm sorry, the 8 question was a little awkward.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Well, what's your 11 understanding of -- now that you've read 12 this section, you've read the letter, 13 what was your understanding of the FDA's 14 views on -- on the necessity of the 15 RiskMAP being approved to assure the safe 16 use of Actiq?</p> <p>17 MR. DIAMANTATOS: Objection. 18 Form. Foundation. Calls for 19 speculation.</p> <p>20 THE WITNESS: So if -- that 21 it was approved under limited 22 distribution and restrictions, and 23 it's -- what's missing here is, 24 under the big scope of Subpart H,</p>	<p>1 sponsor as Anesta Corp., a 2 subsidiary of Cephalon, Inc. And 3 the date on the lower right is 4 February 9, 1999. The document 5 number is TEVA_MDL_A_03272088.</p> <p>6 BY MR. CRAWFORD:</p> <p>7 Q. Was this the RiskMAP that 8 you recall that was in place when you 9 joined the company, for Actiq?</p> <p>10 A. No. When I joined, it was 11 still under Anesta. And so we must have 12 submitted this after I joined.</p> <p>13 Q. I see.</p> <p>14 So this was in place, at 15 least, early in your tenure there?</p> <p>16 A. Yes.</p> <p>17 Q. But you joined -- you joined 18 Cephalon in 2000, right?</p> <p>19 A. That's correct.</p> <p>20 Q. And this is dated February 21 9, 1999, and it does reference Cephalon.</p> <p>22 But this is basically the 23 one that you were operating under when 24 you were there?</p>
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<p>1 is that if it's not, then it can 2 be -- then it gives the FDA the 3 authority to then pull back the 4 approval.</p> <p>5 And that's -- you're missing 6 that section here. But that's the 7 intention.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Thank you for filling that 10 in. All right.</p> <p>11 MR. CRAWFORD: 601 next.</p> <p>12 MR. JENSEN: This will be 13 Exhibit-7.</p> <p>14 - - -</p> <p>15 (Whereupon, Teva-Marchione 16 Exhibit-7, 17 TEVA_MDL_A_03272088-117, was 18 marked for identification.)</p> <p>19 - - -</p> <p>20 MR. CRAWFORD: What we 21 marked here is a document 22 entitled, Risk Management Program 23 for Actiq, which is referenced in 24 the top. And then lists the drug</p>	<p>1 A. So it does have --</p> <p>2 MR. DIAMANTATOS: Objection 3 to form.</p> <p>4 Go ahead.</p> <p>5 THE WITNESS: It does have 6 February 9, but the August 1st is 7 telling me -- so the issue is, 8 going back to the approval letter, 9 if a single word changes, the FDA 10 would then need approval.</p> <p>11 So this is an instance where 12 we tried to keep the date -- we 13 tried to minimize any changes 14 whatsoever, because it wasn't yet 15 approved and the FDA wouldn't 16 approve it.</p> <p>17 So that's why you have two 18 dates on this. We added a 19 separate date, but we didn't want 20 to change the February 9th date 21 because -- because every single 22 letter was considered a change.</p> <p>23 Does that make sense?</p> <p>24 BY MR. CRAWFORD:</p>

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<p>1 Q. Yes.</p> <p>2 Is it your understanding,</p> <p>3 though, that this version, at least, was</p> <p>4 approved by the FDA?</p> <p>5 A. No, it was not.</p> <p>6 Q. So you're saying that the</p> <p>7 February 9th, 1999 one is the approved</p> <p>8 one?</p> <p>9 A. Probably, yes.</p> <p>10 Q. All right.</p> <p>11 MR. CRAWFORD: Let's take a</p> <p>12 quick break, if we can.</p> <p>13 VIDEO TECHNICIAN: Going off</p> <p>14 the record at 10:34 a.m.</p> <p>15 - - -</p> <p>16 (Whereupon, a brief recess</p> <p>17 was taken.)</p> <p>18 - - -</p> <p>19 VIDEO TECHNICIAN: We're</p> <p>20 back on the record at 10:46 a.m.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. All right. We took a look,</p> <p>23 and I think we found the February 9th,</p> <p>24 1999 RiskMAP. So we're getting copies</p>	<p>1 A. Yes.</p> <p>2 Q. And the goal, it states, is</p> <p>3 the primary goal of making every</p> <p>4 reasonable effort to reduce the risk of</p> <p>5 potential untoward events in the</p> <p>6 unintended populations, to the extent</p> <p>7 possible. This program includes the</p> <p>8 following -- and then skipping down --</p> <p>9 comprehensive, professional patient</p> <p>10 caregivers and child educational</p> <p>11 programs, interventions at the point of</p> <p>12 dispensing, and Class II status for</p> <p>13 Actiq.</p> <p>14 So was it your</p> <p>15 understanding, as well, that the goal of</p> <p>16 this program was to reduce the risk of</p> <p>17 untoward events in unintended</p> <p>18 populations?</p> <p>19 MR. DIAMANTATOS: Objection</p> <p>20 to form. Foundation. Calls for</p> <p>21 speculation.</p> <p>22 THE WITNESS: That was one</p> <p>23 of three reasons.</p> <p>24 BY MR. CRAWFORD:</p>
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<p>1 made, and we'll mark that -- we're going</p> <p>2 to mark it as Exhibit-8 once we get it,</p> <p>3 and then we'll give you an opportunity to</p> <p>4 take a look at it. So I won't ask you</p> <p>5 anything about it right now.</p> <p>6 Let's proceed on with</p> <p>7 Exhibit-7. This essentially was the</p> <p>8 RiskMAP version that you were working off</p> <p>9 of when you -- after you arrived at</p> <p>10 Cephalon, right?</p> <p>11 MR. DIAMANTATOS: Objection.</p> <p>12 Form.</p> <p>13 THE WITNESS: I believe so.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Okay. So I'd like to delve</p> <p>16 into this.</p> <p>17 On Page 5, under</p> <p>18 introduction, it says, The Actiq risk</p> <p>19 management program, RMP, has been</p> <p>20 designed to address three potential risk</p> <p>21 situations.</p> <p>22 And one risk situation,</p> <p>23 you'll agree with me, is diversion and</p> <p>24 abuse, correct?</p>	<p>1 Q. What was the one reason --</p> <p>2 MR. DIAMANTATOS: Objection.</p> <p>3 Form.</p> <p>4 BY MR. CRAWFORD:</p> <p>5 Q. -- that you're referring to?</p> <p>6 A. What you just -- what you</p> <p>7 just -- I'm going back to your question.</p> <p>8 Q. Right.</p> <p>9 A. I'm sorry, can you repeat</p> <p>10 it?</p> <p>11 Q. I think you're right.</p> <p>12 There were basically three</p> <p>13 reasons for the RiskMAP program. One of</p> <p>14 them was for prevention of diversion and</p> <p>15 abuse, correct?</p> <p>16 A. That's correct.</p> <p>17 Q. So I think that's the main</p> <p>18 focus I'm going to have with regard to</p> <p>19 looking through this. I don't want to go</p> <p>20 through every single word of it, so I'm</p> <p>21 going to kind of direct more towards that</p> <p>22 reason.</p> <p>23 Below that, it says, This</p> <p>24 document provides details and</p>

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<p style="text-align: right;">Page 90</p> <p>1 implementation tactics for all elements 2 of the Actiq risk management program. No 3 single element can provide the complete 4 answer to reducing risk. A lengthy 5 series of events must occur in sequence 6 before a risk can occur, yet any one of 7 multiple RMP elements can intervene to 8 interrupt the sequence and prevent the 9 risk event. Redundancy of program 10 elements is one measure used to 11 strengthen the effectiveness of the RMP. 12 The purpose of the RMP is to ensure the 13 safe use of this product.</p> <p>14 So is it your understanding 15 that the RiskMAP was -- had a, I would 16 say, elements, redundant elements, to 17 make sure that Actiq was used safely?</p> <p>18 MR. DIAMANTATOS: Objection 19 to form. Foundation. 20 Speculation.</p> <p>21 THE WITNESS: That was 22 the -- that's what the FDA said 23 the intention of this document 24 was, yes.</p>	<p style="text-align: right;">Page 92</p> <p>1 A. That's correct. Reporting 2 to the FDA, yes. 3 Q. But other departments, it 4 was their job to make sure these elements 5 were implemented, right? 6 A. That's correct. 7 Q. And that would include sales 8 and marketing, right? 9 A. That's correct. 10 Q. And they would report to you 11 how they were doing in complying with the 12 RiskMAP, and you would assemble that, or 13 your underlings would, into a report to 14 the FDA? 15 A. That's correct. 16 Q. All right. Good. Fair 17 enough. 18 It does say, There are key 19 messages for the RiskMAP. There are 20 several key messages repeated throughout 21 the RMP, which are listed below. 22 Proper patient selection and 23 prevention of diversion and abuse 24 messages look like they are some of the</p>
<p style="text-align: right;">Page 91</p> <p>1 BY MR. CRAWFORD: 2 Q. And do you believe, when you 3 were -- you were in charge of collecting 4 up information and submitting quarterly 5 reports to the FDA about how things were 6 progressing with regard to the operation 7 of the RiskMAP, right? 8 A. That's correct. 9 Q. And so you -- was it your 10 understanding that the RiskMAP contained 11 certain elements and programs that were 12 redundant to try to prevent any untoward 13 effects from the drug?</p> <p>14 MR. DIAMANTATOS: Objection. 15 Form.</p> <p>16 THE WITNESS: That was the 17 FDA's intention.</p> <p>18 BY MR. CRAWFORD: 19 Q. Okay. And your job was to 20 make sure that the company was -- one of 21 your jobs was to make sure that the 22 company was trying to implement those 23 mechanisms, right? Or at least report to 24 the FDA about how the company was doing?</p>	<p style="text-align: right;">Page 93</p> <p>1 messages that the FDA wanted to convey, 2 right? 3 MR. DIAMANTATOS: Objection 4 to form. Foundation. Calls for 5 speculation. 6 THE WITNESS: That's what it 7 says -- 8 BY MR. CRAWFORD: 9 Q. According to this letter? 10 A. According to this document. 11 Q. Right. And one of the 12 proper patient selection messages listed 13 on the next page, under the second bullet 14 point, is that, Actiq is specifically 15 indicated solely for the treatment of 16 breakthrough cancer pain in chronic 17 opioid-tolerant patients. 18 Is that one of the messages 19 the FDA wanted the company to convey? 20 MR. DIAMANTATOS: Objection 21 to form. Foundation. Calls for 22 speculation. 23 THE WITNESS: That's what 24 this document says, yes.</p>

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1	BY MR. CRAWFORD: Q. And also for prevention of diversion/abuse messages, the FDA wanted the company to convey that Actiq may be habit forming, right?	1 sure it was used safely, right? 2 MR. DIAMANTATOS: Objection 3 to form. Foundation. Calls for speculation.
6	MR. DIAMANTATOS: Objection to form. Calls for speculation.	5 THE WITNESS: That's what it says in this document, yes.
8	THE WITNESS: That's what this document says.	7 BY MR. CRAWFORD: 8 Q. And what you're saying is there was another department within 9 Cephalon that -- that was in charge of 10 DEA compliance, right?
10	BY MR. CRAWFORD: 11 Q. And then it references, too, under that bullet point there, that Actiq is a Class II medication, right?	12 MR. DIAMANTATOS: Objection. 13 Form. Mischaracterizes the 14 witness's testimony.
14	A. That's what this document says.	15 THE WITNESS: What I was 16 saying is I don't know the 17 specifics of the requirements 18 under the C-II. And there was 19 another department that would 20 oversee that.
16	Q. Is it your understanding that Actiq was a Class II medication?	21 BY MR. CRAWFORD: 22 Q. All right. So that was 23 the -- was it called the compliance department or DEA compliance department?
18	A. Yes, it was.	
19	Q. Let's go to Page 9 of the RiskMAP, at the bottom, under labeling.	
21	And then it says, C-II, Schedule II, Classification 3.1.	
23	It says, Actiq will be a C-II product, consistent with other	
	Page 95	Page 97
1	strong opioids such as fentanyl, morphine, Oxycodone and hydromorphone-based products. C-II is the most restrictive classification available, and raises the overall level of vigilance and surveillance by all parties involved with the product.	1 A. I don't know the formal name. But yes.
8	So was it your understanding that the FDA -- well, let's hear, what is your understanding of what a Class II product is and what restrictions are imposed upon it?	2 Q. That was their basic function --
13	A. The details of that is more for DEA people. I was more focused on the restrictions from under the RiskMAP.	3 A. I believe so.
16	So I think there's particular levels of people who can prescribe C-II. I don't know all the details, because it's not my area of expertise.	4 Q. -- was to ensure that the company was complying with all the Class II requirements?
21	Q. Understood.	5 A. That's my understanding.
22	So the FDA wanted the Schedule II classification to be another tool, probably a redundant tool, to make	6 Q. Right. And do you know who was in charge of that department?
23		7 Was it Colleen McGinn? Does that name seem familiar?
24		8 A. It seems familiar.
		9 Q. And would they -- would the DEA compliance department, or whatever it's called, when you put your quarterly reports together, would they be one of the departments that would provide you with input?
		10 MR. DIAMANTATOS: Objection to form.
		11 THE WITNESS: I believe so. I'd have to remember the

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<p style="text-align: right;">Page 98</p> <p>1 specifics. It's been a while. 2 BY MR. CRAWFORD: 3 Q. But your department, or you 4 personally, didn't have any 5 responsibility for making sure that the 6 company was complying with the Class II 7 or DEA requirements, right? 8 A. That's correct. 9 Q. But it is a component of the 10 RiskMAP, so it would be part of your 11 reporting to the FDA regarding the Class 12 II issue? 13 A. I don't remember exactly 14 what had to be reported for that. I'd 15 have to look at this. 16 Once it's scheduled, it 17 doesn't change. So it may just be 18 acknowledging that it has to be 19 scheduled. 20 Q. Yeah, let's move on. And if 21 you see something that had to be reported 22 about it, why don't we flag that? 23 A. That's fine. 24 Q. Fair enough.</p>	<p style="text-align: right;">Page 100</p> <p>1 Form. Foundation. 2 THE WITNESS: I think it was 3 one of the elements. I wouldn't 4 say it was the primary. 5 BY MR. CRAWFORD: 6 Q. Again, there were redundant 7 elements to try to make sure that the 8 drug was used as safely as possible in 9 the RiskMAP, right? 10 A. That's correct. 11 Q. Let's go to Page 12. 12 Under 4.1, Key Message 13 Points, the RiskMAP states, The education 14 of physicians, nurses, pharmacists, 15 caregivers and patients on the safe use 16 of Actiq is an integral part of the Actiq 17 risk management program. 18 Again, it was your 19 understanding that that was an integral 20 part of the RiskMAP and the company's 21 obligations, right? 22 A. What was? The educational 23 program? 24 Q. The education of doctors --</p>
<p style="text-align: right;">Page 99</p> <p>1 So the next page, it says, 2 right after the bullet points, The status 3 of Actiq -- is it pronounced Actiq or 4 Actiq? How do you pronounce it? 5 A. Officially, it was Actiq. 6 Q. All right. 7 So the status of Actiq as a 8 C-II product is the primary risk 9 management element that a third potential 10 risk event, the potential of diversion 11 on/or abuse -- I don't think I read that 12 right. Start again. 13 The status of Actiq as a 14 Class II product is the primary risk 15 management element against the third 16 potential risk event - the potential for 17 diversion and/or abuse. 18 So is it your view that the 19 RiskMAP that you were involved with 20 understood that the Class II 21 classification was an important element, 22 a primary element, for making sure that 23 the drug was not abused? 24 MR. DIAMANTATOS: Objection.</p>	<p style="text-align: right;">Page 101</p> <p>1 A. Yes. 2 Q. -- nurses, pharmacists, et 3 cetera, right? 4 A. That's correct. 5 Q. And one of the messages was 6 prevention and diversion of abuse 7 messages, right? 8 A. That's correct. 9 Q. And then the educational 10 programs for physicians, nurses, 11 pharmacists, caregivers and patients will 12 also reinforce the following. 13 One point is efficacy and 14 side effects of the product, right? 15 A. That's correct. 16 Q. And then turning to Page 13, 17 it says, These key educational messages, 18 primarily focusing on safety, are 19 provided to the physicians, nurses and 20 pharmacists through the communication 21 vehicles which are discussed on the 22 following pages. 23 Do you understand what the 24 RiskMAP means by "communication vehicle"?</p>

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1	A. Yes.	A. That's correct.
2	Q. So they are listed here.	Q. That was at least what the
3	One would be Actiq speakers	RiskMAP -- the RiskMAP, it was required
4	bureau medical education programs, right?	by the FDA, but it's something that
5	A. Yes.	Anesta, and, I guess, the subsequent NDA
6	Q. And the goal of those	holders, were agreeable to doing, right?
7	programs, under the RiskMAP, would be to	Or was this just something
8	educate doctors on these messages that we	done because you were told to do it?
9	just went over, correct?	MR. DIAMANTATOS: Objection.
10	A. I'm just reading this. Give	Form. Foundation. Calls for
11	me one second.	speculation.
12	I'm sorry, can you repeat	THE WITNESS: By taking over
13	the question again? I'm sorry. I just	the NDA, we had to agree to do
14	wanted to read that section before --	this, yes.
15	Q. Please do. If you need to	BY MR. CRAWFORD:
16	read something, take your time to do	Q. And take over those
17	that.	responsibilities?
18	A. So if you could ask the	A. That's correct.
19	question again.	Q. Okay. Thank you.
20	Q. Sure.	And then one of the other
21	And the goal of the programs	communication vehicles would be
22	under the RiskMAP would be to educate	publications, under 4.4, correct?
23	doctors on these messages that we just	A. That's what it says here.
24	went over, correct?	Q. Right. And the
	Page 103	Page 105
1	A. That was one of the -- that	publications, it says, will include
2	was one of the elements, to get the	messages that reinforce elements of the
3	risks -- the information on the risks	RiskMAP, right?
4	out. It was a tool.	A. That's what it says here.
5	Q. Right. So the idea is to	Q. And then it lists a number,
6	use these speakers programs to educate	in the next few pages, of publication
7	doctors on the risks and the messages	communication vehicles that the company
8	that are outlined in the RiskMAP, right?	might utilize to get across its messages.
9	MR. DIAMANTATOS: Objection.	Is that how you understood
10	Form.	the program was to operate?
11	THE WITNESS: So as I'm	A. That's what it says here.
12	reading this, they want to train	Q. But this is a program that
13	professionals to train others. So	was intended to ensure the safe use of
14	it was kind of a two-level	Actiq, right?
15	element.	MR. DIAMANTATOS: Objection.
16	That's why I was trying to	Form. Foundation.
17	be clear.	BY MR. CRAWFORD:
18	BY MR. CRAWFORD:	Q. Help ensure, anyway?
19	Q. Right. It says those people	A. Help ensure, yes.
20	that are trained, these groups, will then	Q. Right. All right. Under
21	be called upon to educate the respective	Page 15, 5.0, Actiq Launch Program, the
22	peers and patients, via presentations in	RiskMAP states, Actiq will target a
23	local, state, regional and national	relatively small group of clinicians.
24	settings, correct?	The emphasis of the promotion will be

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<p>1 highly educational.</p> <p>2 That's what was intended in</p> <p>3 promoting the drug, right?</p> <p>4 MR. DIAMANTATOS: Objection.</p> <p>5 Form. Foundation.</p> <p>6 BY MR. CRAWFORD:</p> <p>7 Q. Through the RiskMAP?</p> <p>8 MR. DIAMANTATOS: Objection.</p> <p>9 Form. Foundation. Calls for</p> <p>10 speculation.</p> <p>11 THE WITNESS: This talks</p> <p>12 specifically at launch, yes.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. But even after launch,</p> <p>15 did -- was the education supposed to stop</p> <p>16 or was that supposed to continue</p> <p>17 throughout the marketing of the drug?</p> <p>18 MR. DIAMANTATOS: Objection.</p> <p>19 Form. Foundation. Calls for</p> <p>20 speculation.</p> <p>21 THE WITNESS: I just wanted</p> <p>22 to find where else it mentioned</p> <p>23 that. Because you just directed</p> <p>24 me to this section for launch.</p>	<p>1 interpretation of the company.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. All right.</p> <p>4 A. I can't say for -- you know,</p> <p>5 it's not specified.</p> <p>6 Q. All right. Let's go to the</p> <p>7 next page, 16.</p> <p>8 It talks about the oncology</p> <p>9 sales specialists. Cephalon, Inc. sales</p> <p>10 organization, full-time oncology sales</p> <p>11 specialists have been placed in the field</p> <p>12 to personally call on the target</p> <p>13 audience. The oncology sales specialists</p> <p>14 are the primary day-to-day link to the</p> <p>15 physicians, nurses and pharmacies who</p> <p>16 will be using the product. The oncology</p> <p>17 sales specialists play a key role in</p> <p>18 implementing the RiskMAP.</p> <p>19 Now, your understanding that</p> <p>20 in implementing this RiskMAP plan, that</p> <p>21 the sales representatives would play a</p> <p>22 key role in disseminating the RiskMAP</p> <p>23 messages.</p> <p>24 A. That's what it says in this</p>
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<p>1 BY MR. CRAWFORD:</p> <p>2 Q. All right. Take your time,</p> <p>3 too. I don't want to rush you through</p> <p>4 this.</p> <p>5 A. So this document</p> <p>6 specifically says at launch. The</p> <p>7 interpretation, I believe, is to take it</p> <p>8 beyond that.</p> <p>9 Q. Right. The educational</p> <p>10 would be messages to doctors?</p> <p>11 A. But it's not specified in</p> <p>12 the RiskMAP, in the REMS or RiskMAP.</p> <p>13 Q. But the intent is that the</p> <p>14 educational aspect will continue even</p> <p>15 after launch --</p> <p>16 MR. DIAMANTATOS: Objection</p> <p>17 to form. Foundation.</p> <p>18 BY MR. CRAWFORD:</p> <p>19 Q. -- in your view?</p> <p>20 MR. DIAMANTATOS: Calls for</p> <p>21 speculation.</p> <p>22 THE WITNESS: It's not</p> <p>23 written in here that way. So it</p> <p>24 was -- I believe it was the</p>	<p>1 document.</p> <p>2 Q. And it does say oncology</p> <p>3 sales specialist there.</p> <p>4 Cephalon didn't really have</p> <p>5 an oncology sales specialist, did it --</p> <p>6 MR. DIAMANTATOS: Objection.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. -- at the time?</p> <p>9 MR. DIAMANTATOS: Objection</p> <p>10 to form.</p> <p>11 BY MR. CRAWFORD:</p> <p>12 Q. They were more the pain</p> <p>13 detailing people, right?</p> <p>14 MR. DIAMANTATOS: Objection.</p> <p>15 Form.</p> <p>16 THE WITNESS: I don't</p> <p>17 remember the exact title, but it</p> <p>18 was a different -- they had</p> <p>19 different titles than this.</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. But it would still mean</p> <p>22 that -- whatever the name was of the</p> <p>23 sales specialists, the intent was that</p> <p>24 they would -- when they called upon</p>

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<p>1 doctors to promote the drug, they would 2 be the ones to convey the RiskMAP 3 messages, right?</p> <p>4 MR. DIAMANTATOS: Objection.</p> <p>5 Form. Foundation.</p> <p>6 THE WITNESS: That's implied, but it doesn't specify it in the document.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Because it's a different name?</p> <p>12 A. Exactly.</p> <p>13 Q. I think, and I could be wrong, but I think there was actually a supplemental change that the FDA approved to change the name of the specialists.</p> <p>17 Do you recall that at all?</p> <p>18 A. I don't know -- I don't know -- I was trying to remember if they approved any of it. So I just don't remember.</p> <p>22 I know we submitted the change. But I just don't remember if it was approved.</p>	<p>1 Form.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. -- in your view?</p> <p>4 MR. DIAMANTATOS: Objection.</p> <p>5 Form. Foundation.</p> <p>6 THE WITNESS: No, not necessarily.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. How is that different than providing samples?</p> <p>11 MR. DIAMANTATOS: Objection.</p> <p>12 Form. Foundation.</p> <p>13 THE WITNESS: Because it could be controlled better than just handing out samples. So it's a more controlled distribution.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. All right. Moving on to Page 22, 8.0, Surveillance goals and activities.</p> <p>21 The goals of the Actiq surveillance and monitoring program are to determine the effectiveness of the Actiq risk management program by</p>
<p>1 Q. All right. Thank you.</p> <p>2 Page 21, part of the RiskMAP, under 7.0, is that product samples will not be made available.</p> <p>5 Do you know why that was an important component of the RiskMAP?</p> <p>7 MR. DIAMANTATOS: Objection to form. Foundation. Calls for speculation.</p> <p>10 THE WITNESS: I don't know what was in the FDA's mind, why they specified that, to be honest. I can't say what they were thinking.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Okay. But you know that this plan prohibited the dissemination or providing of samples of Actiq, right?</p> <p>19 A. That's what it says here, yes.</p> <p>21 Q. And would that include providing coupons or vouchers to get free samples of the product --</p> <p>24 MR. DIAMANTATOS: Objection.</p>	<p>1 monitoring the potential incidence and outcome of child accidental ingestion, potential product use among opioid nontolerant populations, off-label use, and possible diversion and abuse; trigger interventions when problems are discovered; and make modifications to the Actiq risk management program to improve its effectiveness.</p> <p>10 So it was your understanding that, as part of this program, there was some kind of surveillance and monitoring program in place?</p> <p>14 A. Yes, there was.</p> <p>15 Q. And what department was that run out of?</p> <p>17 MR. DIAMANTATOS: Objection to form.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. Was it quality assurance?</p> <p>21 MR. DIAMANTATOS: Objection. Form.</p> <p>23 THE WITNESS: Safety had, for instance, had its own</p>

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<p>1 processes; if they heard 2 something, they would respond. So 3 each stream of processes had 4 evaluation by the initial 5 department, and then quality would 6 then check on that process.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. And to initiate 9 modifications, if the company saw that 10 there was some shortcomings in the 11 program, it was free to make 12 modifications, so long as they submitted 13 them to the FDA and they were approved, 14 right?</p> <p>15 MR. DIAMANTATOS: Objection. 16 Form.</p> <p>17 THE WITNESS: That was the 18 interpretation of this document.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. And, again, one of the 21 objects -- or goals of the Actiq 22 surveillance monitoring program was to 23 monitor the off-label use of the product, 24 right?</p>	<p>1 Form. Mischaracterizes the 2 witness's testimony. Foundation. 3 THE WITNESS: Can you repeat 4 the question again?</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. Yes. 7 So somebody who used the 8 drug who didn't have cancer, that would 9 be an off-label use of the drug?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Form. Vague.</p> <p>12 THE WITNESS: I have to 13 be -- I'm being careful, because 14 if it's prescribed, that's -- 15 that's between a physician and a 16 patient.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. Right. I understand what 19 you're saying. 20 So doctors can make the 21 choice to -- they're not breaking any law 22 by prescribing it off label for a use 23 that's not in the approved indications, 24 right?</p>
<p>1 MR. DIAMANTATOS: Objection. 2 Form. Foundation.</p> <p>3 THE WITNESS: That's what 4 this document asks for, yes.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. And this is a document that 7 the company was required to follow as a 8 condition for continued -- being allowed 9 to continue to market Actiq, right?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Form. Foundation. Asked and 12 answered.</p> <p>13 THE WITNESS: Yes.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. And off-label use means -- 16 what does that mean to you?</p> <p>17 A. That means it's documented 18 that somebody who doesn't meet the 19 labeled criteria is using the product.</p> <p>20 Q. So if somebody -- off-label 21 use might be somebody who is a noncancer 22 patient that used the product; that would 23 be off label?</p> <p>24 MR. DIAMANTATOS: Objection.</p>	<p>1 A. That's correct. 2 Q. It's just that the company 3 can't market it to the doctors for an 4 off-label use; that's the rule, right?</p> <p>5 A. That's correct. 6 Q. And so for Actiq, it's 7 approved, in part, to treat breakthrough 8 pain in patients with cancer, right? 9 A. Who are non -- who are 10 opioid tolerant, yes. 11 Q. Right. Who are opioid 12 tolerant. 13 So one of the -- so if 14 somebody without cancer uses the drug or 15 is prescribed the drug, it might be legal 16 for the doctor to do that, but it is an 17 off-label use? That would be -- 18 A. Correct. 19 Q. -- one off-label use, 20 correct? 21 And somebody who wasn't 22 opioid tolerant, meaning they hadn't used 23 opioids before, that would be an 24 off-label use, right?</p>
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<p>1 A. That's my understanding.</p> <p>2 Q. And if it was used for</p> <p>3 something other than breakthrough pain,</p> <p>4 which is in the indication, then that</p> <p>5 would, again, be an off-label use?</p> <p>6 A. That's my understanding.</p> <p>7 Q. On Page -- let's see, the</p> <p>8 bottom of Page 22, there's a direct</p> <p>9 patient feedback section component, chain</p> <p>10 pharmacy callback system. Top of Page</p> <p>11 23, it says, A callback system will be</p> <p>12 used to directly query Actiq patients.</p> <p>13 And, you know, one of the</p> <p>14 queries was whether the patient received</p> <p>15 an Actiq welcome kit.</p> <p>16 Do you see that at the top</p> <p>17 bullet point?</p> <p>18 A. Yes.</p> <p>19 Q. And then it says, The</p> <p>20 partners included in this system include</p> <p>21 Rite Aid, Eckerd, Walgreens and the Merck</p> <p>22 Medco system, right?</p> <p>23 A. That's what it says.</p> <p>24 Q. So this program, or callback</p>	<p>1 (appropriate patient selection) to usage</p> <p>2 by specialties such as surgeons,</p> <p>3 (inappropriate patient selection).</p> <p>4 So based on this, your</p> <p>5 understanding was, the RiskMAP required</p> <p>6 use of this IMS Xponent database to</p> <p>7 analyze the prescribing of the doctors of</p> <p>8 Actiq, right?</p> <p>9 MR. DIAMANTATOS: Objection.</p> <p>10 Form. Foundation.</p> <p>11 Go ahead.</p> <p>12 THE WITNESS: That's what it</p> <p>13 says here, yes.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. But it's your understanding,</p> <p>16 too?</p> <p>17 I mean, I know it says that,</p> <p>18 but the company -- the RiskMAP is</p> <p>19 something that the FDA -- or that was</p> <p>20 required as a condition or part of the</p> <p>21 approval, right?</p> <p>22 A. That's correct.</p> <p>23 Q. And to make changes, you had</p> <p>24 to get -- submit a supplement, and the</p>
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<p>1 system, under the RiskMAP, was to be run</p> <p>2 through those five partners, right?</p> <p>3 A. That's what it says here.</p> <p>4 Q. Right. And then the next</p> <p>5 section, 8.2, IMS Component.</p> <p>6 It says here that,</p> <p>7 Prescription data will be routinely</p> <p>8 monitored. The source of these data will</p> <p>9 be IMS Xponent, the largest sample</p> <p>10 available of Actiq prescriptions,</p> <p>11 segmented by physician specialty, to</p> <p>12 determine prescribing needs. The IMS</p> <p>13 Xponent data sample represents</p> <p>14 prescriptions from over 1 million</p> <p>15 prescribers and over 35,000 retail</p> <p>16 pharmacies. Additionally, IMS Xponent</p> <p>17 captures 60 million mail order</p> <p>18 prescriptions per year.</p> <p>19 These data provide the</p> <p>20 prescriber's name, the physician</p> <p>21 specialty and zip code. These data will</p> <p>22 be analyzed by comparing the proportion</p> <p>23 of prescriptions written by specialties</p> <p>24 such as hematologists/oncologists</p>	<p>1 FDA had to approve any change to this</p> <p>2 RiskMAP, correct?</p> <p>3 A. That's correct.</p> <p>4 Q. Let's go to the next page,</p> <p>5 24, Wholesaler data.</p> <p>6 It does say, Cephalon, Inc.</p> <p>7 will receive information on retail</p> <p>8 pharmacy sales. Additionally, every two</p> <p>9 months -- skipping down to the third</p> <p>10 paragraph there -- Additionally, every</p> <p>11 two months a Cephalon Inc. trade sales</p> <p>12 specialist (wholesaler representative)</p> <p>13 will call on the high-volume Actiq</p> <p>14 wholesalers. This person will request</p> <p>15 information on any additional pharmacies</p> <p>16 which need to be added to the list.</p> <p>17 Information from Cephalon's -- from</p> <p>18 Cephalon's meetings with wholesalers will</p> <p>19 be shared with the oncology sales</p> <p>20 specialists for follow up. The sponsor</p> <p>21 will monitor for compliance at the RMP</p> <p>22 point of dispensing and report violations</p> <p>23 to the FDA quarterly, along with any</p> <p>24 interventions made as a result.</p>

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<p style="text-align: center;">Page 122</p> <p>1 So do you recall if Cephalon 2 had this wholesaler data process in 3 place, reporting process, during the time 4 you were there?</p> <p>5 MR. DIAMANTATOS: Objection. 6 Form. Foundation.</p> <p>7 THE WITNESS: I believe we 8 did.</p> <p>9 My hesitancy is because it 10 evolved. Things were evolving 11 depending upon the year and what 12 was available.</p> <p>13 So you'd have to look at the 14 RiskMAP quarterlies all the way 15 along, how things may have 16 changed. So that's why I'm 17 implying that, in general, this is 18 my understanding, but things 19 could -- and operationally things 20 could have changed.</p> <p>21 The intention was there, and 22 we did -- we did agree to it. And 23 we did implement it. But it may 24 not be exactly like that, as it</p>	<p style="text-align: center;">Page 124</p> <p>1 A. You know, I don't know, to 2 be honest. It wasn't -- I just don't 3 remember, and I don't know how that 4 worked.</p> <p>5 Q. I'll represent, I believe, 6 that the restriction -- there was a 7 restriction, you couldn't sell directly 8 to pharmacies the Actiq.</p> <p>9 But, regardless, my question 10 is, this requirement required the company 11 to kind of look downstream at the 12 wholesalers' customers and do some 13 digging about where there might be some 14 inappropriate distribution of the drug?</p> <p>15 A. That was --</p> <p>16 MR. DIAMANTATOS: Objection. 17 Form. Foundation.</p> <p>18 Go ahead.</p> <p>19 THE WITNESS: That's the 20 requirement of this. I just don't 21 remember how it was implemented. 22 And the reports would tell you 23 that. So that's why I'm hesitant.</p> <p>24 BY MR. CRAWFORD:</p>
<p style="text-align: center;">Page 123</p> <p>1 evolved.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. Just kind of in your own 4 words, what's your understanding of what 5 the company was to do with regard to this 6 wholesaler data tool here?</p> <p>7 MR. DIAMANTATOS: Objection 8 to form.</p> <p>9 THE WITNESS: Just what it 10 says, the sponsor will monitor the 11 compliance, and report violations 12 to the FDA quarterly.</p> <p>13 And I believe that in our 14 quarterly reports, we explained 15 what we did. So we can find those 16 documents to accompany this.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. But they were supposed to 19 kind of do some digging downstream, you 20 know; basically the company sold to 21 wholesalers, pretty much, right, the 22 drug?</p> <p>23 They couldn't sell it 24 directly to pharmacies, could they?</p>	<p style="text-align: center;">Page 125</p> <p>1 Q. Got it. I understand. 2 Thank you.</p> <p>3 Go to 27, Page 27, under 4 9.1.2, under the section, Groups of 5 Prescribers.</p> <p>6 Why don't you take, you 7 know, just a minute or whatever to read 8 this section?</p> <p>9 A. Section 9?</p> <p>10 Q. Yes. 9.1.2. It's under 11 9.1, Off-label usage, it's subsection of 12 9.0, Intervention.</p> <p>13 A. Okay. I'm done.</p> <p>14 Q. All right. Let me just read 15 this into the record. And I just want to 16 get your understanding, in your own 17 words, of how your department or the 18 company interpreted how this was supposed 19 to be implemented.</p> <p>20 It says, If groups of 21 physicians (such as a particular 22 specialty) are identified as having 23 prescribed Actiq inappropriately, and 24 these prescriptions represent potential</p>

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<p style="text-align: center;">Page 126</p> <p>1 off-label usage greater than 15 percent 2 of total quarterly Actiq prescriptions, 3 Cephalon, Inc. will contact the 4 appropriate professional society (i.e., 5 American College of Surgeons, American 6 Society of Anesthesiologists). This 7 letter will outline prescribing concerns 8 and offer to implement an educational 9 program in conjunction with the 10 professional society in a national 11 setting.</p> <p>12 Prescribing patterns will be 13 monitored for the physician groups in 14 question and should the level continue to 15 exceed 15 percent of total Actiq 16 prescriptions for two additional 17 quarters, an aggressive educational 18 campaign will be initiated by mail, 19 clearly warning of the potential 20 liabilities of prescribing Actiq to 21 inappropriate patient populations. 22 So this was a requirement of 23 the RiskMAP, to have this monitoring of 24 groups of prescribers, right?</p>	<p style="text-align: center;">Page 128</p> <p>1 THE WITNESS: I believe so. 2 But if I could see one of 3 the quarterly reports, I could be 4 more specific.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. Can you give me some kind of 7 account about how the company interpreted 8 this 15 percent requirement?</p> <p>9 MR. DIAMANTATOS: Objection. 10 Form. Foundation. Calls for 11 speculation. Assumes facts.</p> <p>12 THE WITNESS: I can tell you 13 exactly if I saw the report.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Right.</p> <p>16 A. I'm just trying to remember, 17 and I don't want to say the wrong thing.</p> <p>18 Q. All right. We'll try to 19 pull a report --</p> <p>20 A. That will be helpful.</p> <p>21 Q. -- and give that to you.</p> <p>22 Thank you. Yes.</p> <p>23 And then the last page here, 24 10.0, on Page 29. It does say, Cephalon,</p>
<p style="text-align: center;">Page 127</p> <p>1 A. That's correct. 2 Q. And do you recall what 3 department there at Cephalon was in 4 charge of implementing this tool? 5 MR. DIAMANTATOS: Objection. 6 Form. Foundation. Assumes facts. 7 BY MR. CRAWFORD: 8 Q. Or mechanism, I would say? 9 MR. DIAMANTATOS: Same 10 objections. 11 THE WITNESS: It may have 12 been from the IMS database. 13 If I looked at the report, I 14 could tell you better. The report 15 describes how we did everything. 16 BY MR. CRAWFORD: 17 Q. But I'm trying to find out 18 what department. 19 Was sales and marketing the 20 department that collected this 21 information and provided it to you for 22 the quarterly report? 23 MR. DIAMANTATOS: Objection. 24 Form. Foundation.</p>	<p style="text-align: center;">Page 129</p> <p>1 Inc. will provide a quarterly report to 2 the FDA compiled from all data collected 3 by the methods described under the Actiq 4 surveillance and monitoring program 5 interventions, see Sections 8.0 and 9.0 6 of the document. This report will 7 describe and provide data and any 8 concerns for child safety, diversion and 9 off-label usage. 10 So that was -- that's the 11 report that you were required to prepare, 12 right? 13 A. That's correct. 14 Q. So one of those components 15 was to provide data and concerns about 16 off-label usage to the FDA, because they 17 wanted to know what was happening, right? 18 A. Yes. 19 MR. CRAWFORD: Can we go off 20 the record for a little bit? I 21 think we might have a quarterly 22 report, and this might be a good 23 time to get that. 24 VIDEO TECHNICIAN: Going off</p>

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<p>1 the record. 11:22 a.m.</p> <p>2 - - -</p> <p>3 (Whereupon, a brief recess</p> <p>4 was taken.)</p> <p>5 - - -</p> <p>6 VIDEO TECHNICIAN: We're</p> <p>7 back on the record at 11:34 a.m.</p> <p>8 - - -</p> <p>9 (Whereupon, Teva-Marchione</p> <p>10 Exhibit-9,</p> <p>11 TEVA_MDL_A_04578988-9017, was</p> <p>12 marked for identification.)</p> <p>13 - - -</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Ms. Marchione, we did find a</p> <p>16 quarterly report, I believe, Exhibit-9,</p> <p>17 dated September 24th, 2003 signed by you.</p> <p>18 It's TEVA_MDL_A_04578988.</p> <p>19 Is this a quarterly report</p> <p>20 that you referred to earlier?</p> <p>21 A. Yes, it is.</p> <p>22 Q. And this was prepared or</p> <p>23 compiled by you or your department,</p> <p>24 right?</p>	<p>1 surveillance and monitoring programs,</p> <p>2 Sections 8 and 9, surveillance goals and</p> <p>3 activities.</p> <p>4 And then it starts with</p> <p>5 direct patient feedback and continues</p> <p>6 through with sections that correspond to</p> <p>7 the actual RiskMAP sections, right?</p> <p>8 A. That's correct.</p> <p>9 Q. So I think my question</p> <p>10 was -- that you wanted to refer to it --</p> <p>11 I think it was dealing with the 15</p> <p>12 percent requirement in the Actiq RiskMAP,</p> <p>13 right?</p> <p>14 A. That's my recollection.</p> <p>15 Q. Yeah. I think that was --</p> <p>16 just so you can pull it up next to it,</p> <p>17 that was Exhibit-7, Page 27, groups of</p> <p>18 prescribers, under off-label usage.</p> <p>19 And I think I had asked you</p> <p>20 exactly how -- how the company</p> <p>21 interpreted and implemented this</p> <p>22 mechanism to evaluate the prescribing by</p> <p>23 these groups of physicians.</p> <p>24 Is there anything -- and</p>
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<p>1 A. That's correct.</p> <p>2 Q. And submitted to the FDA,</p> <p>3 correct?</p> <p>4 A. That's correct.</p> <p>5 Q. And if you could, maybe take</p> <p>6 a few moments to look at it, maybe go to</p> <p>7 the first page, which is at 93.</p> <p>8 It says, Actiq risk</p> <p>9 management program, 17th quarterly</p> <p>10 report, April 1st, 2003 to June 30th,</p> <p>11 2003.</p> <p>12 This was the report that was</p> <p>13 referenced in, I think, Section 10 of the</p> <p>14 RiskMAP document, right?</p> <p>15 A. That's correct.</p> <p>16 Q. And this is a report that</p> <p>17 you would prepare in your ordinary course</p> <p>18 of business, right?</p> <p>19 A. That's correct.</p> <p>20 Q. And this one, in fact, was</p> <p>21 submitted to the FDA?</p> <p>22 A. That's correct.</p> <p>23 Q. And I think the first page</p> <p>24 here, Page 2, actually, it says, Actiq</p>	<p>1 take your time, but is there anything in</p> <p>2 the quarterly report that triggers your</p> <p>3 recollection of how the company might</p> <p>4 have interpreted and utilized and</p> <p>5 implemented that mechanism?</p> <p>6 MR. DIAMANTATOS: Objection</p> <p>7 to form.</p> <p>8 THE WITNESS: Just give me a</p> <p>9 minute, please.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. Take your time.</p> <p>12 This one, actually, I think,</p> <p>13 at Page 11 and 12, seems to skip over the</p> <p>14 9.1.2 section.</p> <p>15 A. That's what I'm looking at.</p> <p>16 Because we did -- oh, God.</p> <p>17 We did always have the 15 percent cutoff.</p> <p>18 There was an IMS printout that listed --</p> <p>19 did we -- wait a second.</p> <p>20 So in Section 8.2.1 on Page</p> <p>21 3, under, NDC Source Prescriber audit, it</p> <p>22 states there, The data from the NDC</p> <p>23 Source Prescriber audit shows that none</p> <p>24 of the nontargeted physician specialties</p>

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<p style="text-align: right;">Page 134</p> <p>1 exceeded 15 percent of the total 2 prescriptions during 2Q03. 3 So the actual documentation, 4 if I remember correctly, you know, was 5 very long and -- but we would get the 6 information and review it and put that 7 statement.</p> <p>8 So it's on Page 3, under 9 8.2.1.</p> <p>10 Q. Right. Okay. So the 11 corresponding section in the Actiq 12 RiskMAP is on Page 23, under 8.2.1, IMS 13 Xponent. That shows a different data 14 source, NDC Source Prescriber audit.</p> <p>15 Is that the reason why 16 that's different than what's required by 17 the RiskMAP?</p> <p>18 A. This is one of those 19 evolving operational things. And maybe 20 the IMS Xponent wasn't available any 21 longer. So I think they switched over to 22 an NDC component.</p> <p>23 Q. Do you know if the FDA ever 24 approved that switch?</p>	<p style="text-align: right;">Page 136</p> <p>1 those historical -- if you looked back in 2 the communication logs, we probably 3 communicated that we were now 4 combining -- using the IMS for the 5 Xponent.</p> <p>6 And that's why we say here 7 explicitly that the nontargeted physician 8 specialties exceeded 15 percent of the 9 total prescriptions.</p> <p>10 And it's one of those things 11 that you have to go back historically and 12 look at all the FDA correspondence to 13 figure out when that changed and why, and 14 we explain that.</p> <p>15 Q. But, I mean, it would have 16 been just as easy to put it under 9.1.2 17 on Page 12, right after 9.1.1, talking 18 about individual prescribers.</p> <p>19 I mean, is there a reason 20 why you couldn't have put it under that 21 section, which is the logical section, 22 because that's where 15 percent is 23 discussed, in that section?</p> <p>24 A. Right. And I believe -- I</p>
<p style="text-align: right;">Page 135</p> <p>1 MR. DIAMANTATOS: Object to 2 form.</p> <p>3 Go ahead.</p> <p>4 THE WITNESS: I doubt it.</p> <p>5 Again, we informed them every time 6 we changed something. But, as I 7 mentioned earlier, they -- we 8 never got, you know, an 9 acknowledgment letter.</p> <p>10 We definitely sent it in 11 writing that -- what we were 12 changing along the way.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Right. But there's nothing 15 in 8.2.1 that talks about the 15 16 percent --</p> <p>17 A. So I think --</p> <p>18 Q. -- specialties. That comes 19 under -- if you look under the RiskMAP on 20 Page 27, that 15 percent is under 9.1.2.</p> <p>21 And you'll agree with me 22 that that section is omitted, 9.1.2, from 23 the report, right?</p> <p>24 A. I agree. And it's one of</p>	<p style="text-align: right;">Page 137</p> <p>1 can't remember exactly, but because they 2 were both kind of looking at the same 3 thing, I think we combined it into that.</p> <p>4 So we could repeat it again, 5 but -- if you looked at the progression 6 of the reports and the communication, it 7 would probably make a lot of sense where 8 things were. We told them we were moving 9 things or what we were doing.</p> <p>10 So we were probably using 11 the same source now to answer both 12 things. So this came up first, and 13 that's why we put it there.</p> <p>14 Q. So was there ever any point 15 in time that you, in one of these 16 reports, reported that there were 17 nontargeted physician specialties that 18 did exceed 15 percent of total 19 prescriptions?</p> <p>20 MR. DIAMANTATOS: Objection.</p> <p>21 Form. Vague as to time.</p> <p>22 BY MR. CRAWFORD:</p> <p>23 Q. At any time.</p> <p>24 A. I think there was one --</p>

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<p style="text-align: right;">Page 138</p> <p>1 MR. DIAMANTATOS: Same 2 objection.</p> <p>3 THE WITNESS: -- quarter, or 4 two. It was later in the -- it 5 was later, you know, towards the 6 end of the marketing or the sales. 7 So I don't know -- I can't 8 exactly -- but we only exceeded it 9 once or twice. That why I wanted 10 you to actually see this, because 11 we never -- I think we 12 initially -- we can find the 13 date -- we never exceeded it 14 except for once or twice.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. All right. And then do you 17 remember what nontargeted specialties 18 exceeded 15 percent in those reports?</p> <p>19 A. I don't remember.</p> <p>20 Q. All right. And what is a 21 nontargeted physician specialty?</p> <p>22 A. I believe -- I believe 23 somewhere down the line we communicated 24 to the agency who -- the groups that</p>	<p style="text-align: right;">Page 140</p> <p>1 So what the FDA -- or what 2 the RiskMAP says is, If groups of 3 physicians (such as a particular 4 specialty) are identified as having 5 prescribed Actiq inappropriately and 6 these prescriptions represent potential 7 off-label usage greater than 15 percent 8 of total quarterly Actiq prescriptions, 9 Cephalon will contact the appropriate 10 professional society.</p> <p>11 A. Right.</p> <p>12 Q. It gives examples, American 13 College of Surgeons, American Society of 14 Anesthesiologists.</p> <p>15 And then you say in your 16 report to the FDA, under 8.2.1, Data from 17 the NDC Source Prescriber audit show that 18 none of the nontargeted physician 19 specialties exceeded 15 percent of the 20 total prescriptions during Q203.</p> <p>21 So the nontargeted physician 22 specialties are specialties that are 23 not -- would not be prescribing the drug 24 as it was indicated, right?</p>
<p style="text-align: right;">Page 139</p> <p>1 they -- I don't know who, I guess, 2 commercial, identified were not 3 prescribing for oncology.</p> <p>4 So it could go beyond 5 oncologists. And so whatever groups that 6 they identified, there's a communication 7 somewhere and why they chose those 8 groups.</p> <p>9 Q. All right. So just turn to 10 Page 27 of Exhibit-7.</p> <p>11 I'm trying to understand 12 about the -- this is 9.1.2.</p> <p>13 A. 27 --</p> <p>14 Q. That would be exhibit, I'm 15 sorry, Exhibit-7, which is the Actiq 16 RiskMAP.</p> <p>17 A. I'm sorry, what page?</p> <p>18 Q. I think you might be in the 19 quarterly report.</p> <p>20 A. You want 27, sorry.</p> <p>21 Q. Yes.</p> <p>22 A. Okay.</p> <p>23 Q. And I'm just trying to 24 understand what you're reporting here.</p>	<p style="text-align: right;">Page 141</p> <p>1 A. It's a commercial question. 2 My understanding is that they were -- 3 they wouldn't target prescribers who 4 weren't prescribing to cancer patients.</p> <p>5 Q. All right. So none of those 6 specialties exceeded 15 percent of total 7 prescriptions, is what you're saying 8 here?</p> <p>9 A. That's correct.</p> <p>10 MR. DIAMANTATOS: Objection. 11 Form.</p> <p>12 THE WITNESS: That's my 13 understanding, yes.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Now, what about the targeted 16 physician specialties, what would they 17 be, for example, like, anesthesiologists?</p> <p>18 A. It was defined -- somewhere 19 in previous communications we defined 20 that. There's so many, you know -- I'd 21 have to look at all the documents.</p> <p>22 Q. Sure. I understand. 23 Is there, like, an SOP or 24 something that may have helped clarify</p>

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<p>1 things?</p> <p>2 A. I don't know. It would be</p> <p>3 with the commercial group, because they</p> <p>4 were giving -- they were doing -- it was</p> <p>5 a marketing research group that was</p> <p>6 giving us this IMS data, and they</p> <p>7 would -- and it may be on file somewhere</p> <p>8 where they would define, you know, what</p> <p>9 their search criteria was and what the</p> <p>10 data were.</p> <p>11 Q. All right. So when you</p> <p>12 did -- when the company did identify some</p> <p>13 nontargeted specialties that exceeded 15</p> <p>14 percent, did they -- are you aware if</p> <p>15 they took the appropriate steps here to</p> <p>16 write letters, or if it exceeded two</p> <p>17 quarters, embark on aggressive</p> <p>18 educational program?</p> <p>19 A. To the best of my</p> <p>20 recollection, what we did was any time we</p> <p>21 were aware of off-label prescribing, we</p> <p>22 sent a letter. It was also a visit by</p> <p>23 the -- it could have been by the sales</p> <p>24 rep or MSL.</p>	<p>1 me, that if you're aware of a group of</p> <p>2 physicians that prescribe Actiq</p> <p>3 inappropriately and they exceed 15</p> <p>4 percent of the total Actiq prescriptions,</p> <p>5 you're required to write a letter, at</p> <p>6 least to the professional society,</p> <p>7 outlining the prescribing concerns and</p> <p>8 offering to implement educational</p> <p>9 programs, right?</p> <p>10 MR. DIAMANTATOS: Objection.</p> <p>11 Form. Asked and answered.</p> <p>12 THE WITNESS: To that point</p> <p>13 is, I think -- I can't remember</p> <p>14 exactly. I think we looked into</p> <p>15 going to the society, and it</p> <p>16 was -- we felt that going to the</p> <p>17 specific doctors who were</p> <p>18 prescribing off label would be</p> <p>19 more effective.</p> <p>20 I don't know if they -- I'd</p> <p>21 have to -- I don't remember. I</p> <p>22 think they did try to go to those</p> <p>23 societies, and, you know, they</p> <p>24 felt that that's not the correct</p>
<p>1 And so we did -- rather than</p> <p>2 going to a group, we wanted specifically</p> <p>3 to target that physician, to make sure he</p> <p>4 was aware of the prescribing. So we --</p> <p>5 so we did it in that way because it was</p> <p>6 easier to identify -- we felt it would be</p> <p>7 more effective to target the actual</p> <p>8 prescriber than to a general group. So</p> <p>9 we did send off-label letters.</p> <p>10 Q. All right. But that's</p> <p>11 9.1.1, that's the individual prescriber</p> <p>12 and you become aware that they're</p> <p>13 prescribing off label, the RiskMAP</p> <p>14 requires a letter sent to the individual</p> <p>15 prescriber, right?</p> <p>16 A. Right.</p> <p>17 Q. And that's on Page 27 here</p> <p>18 of Exhibit-7, correct?</p> <p>19 A. Right.</p> <p>20 Q. That's that mechanism,</p> <p>21 right?</p> <p>22 A. Right.</p> <p>23 Q. But there is an additional</p> <p>24 mechanism in 9.1.2, would you agree with</p>	<p>1 place for it.</p> <p>2 You know, again, this goes</p> <p>3 back to -- when this RiskMAP was</p> <p>4 put together, it was done quickly.</p> <p>5 There was not a lot of research</p> <p>6 behind it. So there's a lot of</p> <p>7 things in here that couldn't</p> <p>8 actually be implemented.</p> <p>9 So what we tried to do is --</p> <p>10 actually, I'd say, 90 percent of</p> <p>11 the time we were overly aggressive</p> <p>12 in going to more specific -- we</p> <p>13 thought that would be better to go</p> <p>14 to each physician, as opposed to a</p> <p>15 group.</p> <p>16 But we did research trying</p> <p>17 to go to those groups, and I don't</p> <p>18 think we could.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. So did you do, like, a mass</p> <p>21 mailing, then, to doctors about -- for</p> <p>22 Actiq at any time?</p> <p>23 I mean, after you</p> <p>24 discovered -- after you reported that</p>

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<p style="text-align: center;">Page 146</p> <p>1 there were a group of physicians, did you 2 do a mass mailing to that group of 3 physicians with information about the 4 proper prescription of the drug?</p> <p>5 A. There were a couple mass 6 mailings done over the course of 7 commercial -- of commercial. And I can't 8 remember what triggered that.</p> <p>9 But that was to -- that was, 10 like, I don't know -- I don't know which 11 groups we chose.</p> <p>12 We talked -- I'm trying to 13 remember. We talked about trying to do 14 that. And I don't know if they could get 15 a list or -- it didn't seem as effective. 16 So we went to the most conservative, and 17 went to all the physicians that were 18 prescribing off label, as opposed to -- 19 that's, basically, what I can remember.</p> <p>20 We've had meetings on it, 21 and I just don't remember the details.</p> <p>22 We tried to comply with 23 every single thing in this document. And 24 when we wouldn't, we went more</p>	<p style="text-align: center;">Page 148</p> <p>1 doctor; you just tried to find doctors 2 who you thought were prescribing off 3 label?</p> <p>4 MR. DIAMANTATOS: Objection. 5 Form. Mischaracterizes testimony. 6 THE WITNESS: We tried to do 7 that. Somewhere there's a memo to 8 the file.</p> <p>9 We tried to do everything 10 that was in there, and we couldn't 11 for some reason. And it's 12 documented. Whether the society 13 wouldn't accept something like 14 that or wouldn't give us the names 15 or -- there were reasons.</p> <p>16 But I just -- I can't 17 remember offhand.</p> <p>18 BY MR. CRAWFORD: 19 Q. But if you sent letters to 20 the FDA -- or to these doctors, it would 21 be reflected in one of your quarterly 22 reports to the FDA, right? 23 A. It is. We talk about how 24 many letters went out that quarter.</p>
<p style="text-align: center;">Page 147</p> <p>1 conservatively.</p> <p>2 Q. Okay. So let's split up 3 Actiq and Fentora.</p> <p>4 For Actiq, was there ever -- 5 you've heard of a Dear Doctor letter, 6 right?</p> <p>7 A. Yes.</p> <p>8 Q. Is that what you're thinking 9 that was sent out, just a form Dear 10 Doctor letter, with the doctor's name on 11 it, or was it -- were you sending 12 individual letters to doctors who you 13 actually knew were prescribing off label?</p> <p>14 MR. DIAMANTATOS: Objection 15 to form.</p> <p>16 THE WITNESS: The latter.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. So you didn't do kind of a 19 general mass mailing to -- when you saw 20 this targeted -- nontargeted specialty 21 that was prescribing it more than 15 22 percent, you didn't do a mass mailing, 23 not knowing whether they were prescribing 24 off label or on label, that particular</p>	<p style="text-align: center;">Page 149</p> <p>1 There was a number --</p> <p>2 Q. Are you looking for a 3 section that -- where you list the 4 doctors or give an account of the 5 individual letters that were sent out to 6 doctors?</p> <p>7 A. Yes. Do you see that?</p> <p>8 Q. I recall seeing something 9 like that in others letters. Maybe it's 10 not here.</p> <p>11 But so the practice would 12 have been, if you did send out letters 13 under 9.2.1 or 9.2.2 or 9.1.2, you would 14 report that to the FDA in one of the 15 quarterly reports, right?</p> <p>16 A. That's my recollection.</p> <p>17 Q. And you would not -- your 18 practice was not to send those letters 19 out and then not tell the FDA you did it, 20 once you found one of these triggers?</p> <p>21 A. I thought, on a quarterly 22 basis, we told how many letters went.</p> <p>23 Q. I'm just trying to -- if I 24 were trying to figure out what was sent</p>

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<p style="text-align: center;">Page 150</p> <p>1 out to doctors that you referenced, I 2 could reference your quarterly reports to 3 get an accounting of what was sent out, 4 right?</p> <p>5 A. That was my recollection, 6 yes.</p> <p>7 Q. And that was your practice 8 to do that?</p> <p>9 A. Yes. It went --</p> <p>10 Q. That's all I really want to 11 know. Because I don't have all the 12 reports with me --</p> <p>13 A. I understand.</p> <p>14 Q. -- but I want to make sure 15 that if I want to try to find out what 16 was sent out --</p> <p>17 A. Yes.</p> <p>18 Q. -- the best source is for me 19 to go back over your quarterly reports 20 and look to see what was sent out, right?</p> <p>21 A. And if it wasn't in the 22 quarterly report, we had a file where we 23 kept -- I don't remember, but we kept 24 all, like, any memos, if something</p>	<p style="text-align: center;">Page 152</p> <p>1 reports reflect that one group only went 2 over 15 percent and what we did. 3 Q. Right. 4 A. I can't remember. 5 But, I guess, I was -- I 6 remember explicitly that it was only that 7 time that it ever reached over -- that 8 only the one group reached over 15 9 percent.</p> <p>10 Q. And you recollect that the 11 report, you reported what you did in 12 response?</p> <p>13 A. Yes.</p> <p>14 Q. So that would be the best 15 way for me to find out what letter -- 16 A. Exactly.</p> <p>17 Q. -- or if anything went out?</p> <p>18 A. And maybe in one of the 19 reports where it hit over 15 percent. 20 But, again, there were so 21 many of them and --</p> <p>22 Q. So many reports?</p> <p>23 A. Yes.</p> <p>24 Q. Yeah. So we'll go back and</p>
<p style="text-align: center;">Page 151</p> <p>1 unusual would happen or whatever, we 2 would always ask for a memo to file. 3 And, like, our safety group 4 had all the -- each department would keep 5 their own files of what they sent. 6 So -- but there was -- I 7 remember there being a RiskMAP file that 8 we kept, I guess, in the document control 9 room that had all the memos and anything 10 unusual that happened. 11 Q. Right. But the letter, the 12 FDA wanted to know, one, if there was a 13 problem, which you identified with the 15 14 percent threshold being reached, and then 15 what you did about it? 16 A. Right, right. 17 Q. So the practice would have 18 been to include it in the quarterly 19 report to the FDA, say, hey, listen, we 20 saw a specialty exceeding 15 percent and 21 we sent a letter out to individual 22 doctors, and you either gave them the 23 number or the names or whatever, right? 24 A. One or two of the quarterly</p>	<p style="text-align: center;">Page 153</p> <p>1 look for that. 2 A. Right. 3 Q. We don't do it today. 4 A. But it was very -- I mean, 5 it only hit it once or twice. 6 Q. All right. What about 7 targeted groups? What about if a 8 targeted group exceeded 15 percent and 9 you determined that potentially over 15 10 percent -- or potentially that the 11 off-label prescribing within that 12 targeted group exceeded 15 percent of 13 total Actiq prescriptions, would that be 14 something that you would monitor and 15 report to the FDA? 16 A. I don't think that was -- I 17 don't think that was one of the 18 requirements for the RiskMAP, because the 19 targeted were patients -- were people who 20 were supposed to be prescribing, right? 21 But any time -- in general, 22 any time we ever became aware, through, 23 like, a serious adverse event -- any time 24 we became aware of an off-label use, we</p>

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<p>1 would send a letter, whatever -- whatever 2 mechanism we heard about it. 3 Q. You mean to an individual 4 doctor? 5 A. Yes. 6 Q. Right. But I'm talking 7 about the groups of physicians 8 requirement, 9.1.2. 9 If you look at the RiskMAP 10 on Page 27, it doesn't talk about 11 targeted or nontargeted doctors -- 12 A. Right. 13 Q. -- you're basically saying 14 that you did not have to monitor the 15 off-label usage for specialties that were 16 targeted, right? 17 A. That's correct. That's not 18 required. 19 But we did -- because it's a 20 redundant document, we did, regardless if 21 they were in the target or nontarget, if 22 we became aware of an off-label use, then 23 we would send a letter. 24 So this is just saying</p>	<p>1 to form. 2 THE WITNESS: That's 3 correct. 4 BY MR. CRAWFORD: 5 Q. So what if a group of 6 anesthesiologists, what if you look at 7 that targeted group, and you look at -- 8 you determined that over 15 percent -- 9 the prescriptions from that group 10 potentially exceeded 15 percent of all 11 total Actiq prescriptions that were off 12 label, wouldn't you have to take the 13 corrective action under 9.1.2 to inform 14 the professional societies and offer up 15 these educational programs? 16 MR. DIAMANTATOS: Objection 17 to form. 18 THE WITNESS: So -- 19 BY MR. CRAWFORD: 20 Q. Under the RiskMAP? 21 MR. DIAMANTATOS: Objection 22 to form. 23 THE WITNESS: I'm not the 24 right person to answer this.</p>
<p style="text-align: center;">Page 155</p> <p>1 that -- this is saying that you're 2 allowed to go to targeted, because that's 3 the people prescribing for oncology. 4 Q. Right. 5 A. So that's fine. 6 But the FDA, the intention 7 of this was to look at the nontargeted 8 group, and if they were prescribing over 9 15 percent, that's when the FDA became 10 concerned. 11 Q. What about -- what if a 12 targeted group, say -- I mean, targeted 13 groups, as far as I understand -- that 14 Cephalon designated as target groups were 15 not only oncologists, but they also 16 designated anesthesiologists -- 17 A. Right. 18 Q. -- as a targeted group, 19 right? 20 A. Right. 21 Q. So that meant that Cephalon 22 felt it could legitimately detail and 23 promote to those -- to that group, right? 24 MR. DIAMANTATOS: Objection</p>	<p style="text-align: center;">Page 157</p> <p>1 But there's an IMS ability 2 of seeing, like, what each -- I 3 don't think they could find that 4 out. I think that's why it was 5 written this way. 6 So they could see what 7 groups were prescribing, and 8 when they could infer it was off 9 label because it was not targeted. 10 But I don't think they 11 could -- at least back then, I 12 don't think they could tell, like, 13 if that psychiatrist was 14 prescribing on label, off label. 15 Because I think that's a HIPAA 16 thing, or whatever. 17 BY MR. CRAWFORD: 18 Q. I see what you mean. 19 So you're basically saying 20 that for the, quote, targeted -- look at 21 9.1.2 on 27. 22 They don't talk about 23 targeted or nontargeted doctors, right? 24 That's a Cephalon interpretation, or how</p>

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<p>1 they implemented this provision, right?</p> <p>2 A. Right.</p> <p>3 Q. But it does talk about if it</p> <p>4 exceeds 15 percent --</p> <p>5 A. Right.</p> <p>6 Q. -- to inform professional</p> <p>7 societies, right?</p> <p>8 A. Right.</p> <p>9 Q. And one of the societies is</p> <p>10 the American Society of</p> <p>11 Anesthesiologists, right?</p> <p>12 So if Cephalon thought that</p> <p>13 anesthesiologists were a targeted group</p> <p>14 and didn't have to look at whether they</p> <p>15 were prescribing it off label within that</p> <p>16 group, then why is the FDA saying that if</p> <p>17 that group exceeds 15 percent, that they</p> <p>18 need to go to them and educate them?</p> <p>19 MR. DIAMANTATOS: Objection.</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. I don't understand that.</p> <p>22 MR. DIAMANTATOS: Objection.</p> <p>23 Form. Foundation. Calls for</p> <p>24 speculation.</p>	<p>1 That was my understanding.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. Okay. Sure.</p> <p>4 And that -- you get your</p> <p>5 information from other people in the</p> <p>6 company, you didn't know directly, right?</p> <p>7 MR. DIAMANTATOS: Objection</p> <p>8 to form.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Is that correct?</p> <p>11 A. In that particular area,</p> <p>12 yes.</p> <p>13 Q. And would that have come</p> <p>14 from sales and marketing, that</p> <p>15 information about breaking out</p> <p>16 specialties and whether they did off</p> <p>17 label --</p> <p>18 A. It was marketing -- it was</p> <p>19 marketing research.</p> <p>20 Q. Thank you.</p> <p>21 THE WITNESS: Are we done</p> <p>22 with these?</p> <p>23 MR. CRAWFORD: Yes. We</p> <p>24 might refer back later, so go</p>
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<p>1 BY MR. CRAWFORD:</p> <p>2 Q. Can you please explain that</p> <p>3 to the jury?</p> <p>4 MR. DIAMANTATOS: Objection.</p> <p>5 Form. Foundation. Calls for</p> <p>6 speculation. Asked and answered.</p> <p>7 THE WITNESS: I think I</p> <p>8 explained it as best I could.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. All right. So it's also</p> <p>11 your testimony that if it was a targeted</p> <p>12 group, say anesthesiologists or</p> <p>13 oncologists, that IMS didn't have a way</p> <p>14 to find out exactly whether, within that</p> <p>15 targeted group, they were prescribing it</p> <p>16 off label or not?</p> <p>17 MR. DIAMANTATOS: Objection.</p> <p>18 Form. Foundation. Calls for</p> <p>19 speculation. Mischaracterizes the</p> <p>20 witness's testimony.</p> <p>21 THE WITNESS: I just don't</p> <p>22 know IMS -- you know, you'd have</p> <p>23 to ask somebody who specializes in</p> <p>24 that.</p>	<p>1 ahead and stick them face down.</p> <p>2 We marked next here a</p> <p>3 document entitled, Quality</p> <p>4 Assurance Memorandum to QA File,</p> <p>5 from David Brennan, subject,</p> <p>6 Internal audit of Actiq risk</p> <p>7 management program, second quarter</p> <p>8 2003. It copies Tim Sheehan,</p> <p>9 Carol Marchione, Bob Bader and</p> <p>10 Mark Solomon. It is marked</p> <p>11 confidential, D0324.</p> <p>12 - - -</p> <p>13 (Whereupon, Teva-Marchione</p> <p>14 Exhibit-10, No Bates, Quality</p> <p>15 Assurance Memorandum, was marked</p> <p>16 for identification.)</p> <p>17 - - -</p> <p>18 BY MR. CRAWFORD:</p> <p>19 Q. Do you recall seeing an</p> <p>20 audit report before by Mr. Brennan?</p> <p>21 A. Yes.</p> <p>22 Q. And this is dated, it looks</p> <p>23 like it's handwritten, December 2nd,</p> <p>24 2003.</p>

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<p style="text-align: right;">Page 162</p> <p>1 And you're a recipient, 2 right? 3 A. That's correct. 4 Q. And Mr. Brennan was in the 5 quality assurance department? 6 A. That's correct. 7 Q. And he -- is it your 8 understanding that he was doing some kind 9 of compliance audit to see whether the 10 company was complying with the Actiq risk 11 management program, right? 12 A. That's my recollection. 13 Q. And he has here kind of a 14 summary -- executive summary here. And 15 he lists as his objective, Audit Actiq 16 risk management program reporting 17 activities to determine compliance with 18 filing commitments, right? 19 A. Yes, that's correct. 20 Q. And then his conclusion is, 21 Based on the findings of this audit of 22 12th through 15th quarterly reports, 23 Cephalon is not in compliance with the 24 commitments communicated in the risk</p>	<p style="text-align: right;">Page 164</p> <p>1 interim person, or by then did Mr. 2 Raczkowski come into place? 3 A. I think by then it was maybe 4 the chief medical officer, Paul Blake. 5 Q. Paul Blake then. 6 He was there on an interim 7 basis, right, until they could find a 8 full-time regular position? 9 A. He was the -- he oversaw my 10 level above, so yes. 11 Q. All right. So -- but that 12 position was vacant, at the time, right 13 above you still? 14 A. I believe so. 15 Q. So Mr. Raczkowski was not 16 involved at the time this report 17 was prepared? 18 A. I believe so. 19 MR. DIAMANTATOS: Object to 20 form. 21 MR. CRAWFORD: Is the form I 22 mispronounced his name, maybe? BY MR. CRAWFORD: Q. So do you recall receiving</p>
<p style="text-align: right;">Page 163</p> <p>1 management program dated August 1, 2001 2 filed with Actiq NDA Number 20-747. 3 The identified issues will 4 be communicated to regulatory affairs 5 management -- that would be you, correct? 6 A. Or my manager. 7 Q. Okay. And who was that? 8 A. The date -- do we know what 9 date this is? 10 Q. December of '03. 11 A. It could have been Ken White 12 at the time. I'm not quite sure. 13 Q. Was he an interim manager 14 before -- while that seat was vacant that 15 we looked back at the -- 16 A. He was the initial manager. I just don't remember when he left. 18 Q. All right. But I think if 19 you look back at Exhibit-3 -- 20 A. It was vacant? 21 Q. Yes. It says, May 28th, 2003, that that position was vacant above you. So would it have been an</p>	<p style="text-align: right;">Page 165</p> <p>1 this memo? 2 A. Vaguely. 3 Q. And he does go through the 4 audit results, starting on Page 2. I just want to kind of go through a couple of them here and see if you remember these. A. Under 8.1, about midway through, 8.1.1.4A, Rite Aid, Eckerd, Walgreens, Merck Medco, participating chains are not identified in the report. Walgreens is the only chain represented. The RiskMAP process guide indicates CVS ProCare data is included, too, but this does not match current practice. The paragraph of the RiskMAP indicates that this program will only be conducted for the first year of sales. It also indicates that after one year, the company will negotiate with FDA to discontinue the patient survey. Do you know whether the company ever negotiated to discontinue the patient survey?</p>

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<p>1 MR. DIAMANTATOS: Objection. 2 Form. Foundation. Assumes facts. 3 THE WITNESS: I don't 4 remember. But that could have 5 been one of the many 6 communications to the FDA of 7 something we were changing.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Do you recall if the FDA 10 ever signed off on dropping that program?</p> <p>11 MR. DIAMANTATOS: Objection. 12 Form. Assumes facts.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Or negotiated a different 15 program there?</p> <p>16 MR. DIAMANTATOS: Objection. 17 Form. Foundation. Assumes facts.</p> <p>18 THE WITNESS: As I mentioned 19 previously, we -- it seemed like 20 the communication was more 21 one-sided. So we didn't hear 22 back.</p> <p>23 BY MR. CRAWFORD:</p> <p>24 Q. Right. But there was no</p>	<p>1 these things just weren't able to 2 be done.</p> <p>3 BY MR. CRAWFORD: 4 Q. Do you know if the company 5 ever submitted a supplement to try to 6 change the provision to narrow it down to 7 Walgreens?</p> <p>8 A. I believe -- I believe we 9 did. Every time we tried to -- you know, 10 we came across something that was 11 different, we communicated it at some 12 point.</p> <p>13 I'd have to look -- it was 14 so long ago. I would have to look.</p> <p>15 Q. Well, I mean, before this 16 point in time, did the company ever 17 submit some kind of formal application to 18 change the process to narrow the number 19 of partners here that were doing this?</p> <p>20 MR. DIAMANTATOS: Objection. 21 Form. Foundation.</p> <p>22 THE WITNESS: You know, if 23 I -- I'm trying to remember -- of 24 having a phone contact with the</p>
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<p>1 official approval by the FDA of the 2 change?</p> <p>3 MR. DIAMANTATOS: Objection. 4 Form. Assumes facts. Foundation.</p> <p>5 THE WITNESS: No.</p> <p>6 BY MR. CRAWFORD:</p> <p>7 Q. Okay. In fact, was the 8 company only using Walgreens data at the 9 time?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Foundation.</p> <p>12 THE WITNESS: I don't 13 remember.</p> <p>14 I do remember that 15 throughout this there were 16 probably a lot of things that -- 17 going back to things were 18 different. And if he was looking 19 at the original, because it wasn't 20 updated, we couldn't actually do a 21 lot of the things that were 22 required.</p> <p>23 So that's why they're just 24 using Walgreens. Because some of</p>	<p>1 FDA and saying, you know, we've 2 communicated -- and I believe what 3 the project manager told us, well, 4 communicate -- just communicate it 5 and acknowledge it and -- until 6 you would get an approval.</p> <p>7 So it would have to be in my 8 communication logs. We could -- 9 obviously, I was concerned that we 10 weren't getting feedback. And I 11 think that it was communicated 12 that she told me to acknowledge it 13 in writing and then just keep 14 going until you change it.</p> <p>15 I can't say for sure. But 16 that's a recollection I have, 17 because I was concerned that we 18 needed to change certain things.</p> <p>19 BY MR. CRAWFORD: 20 Q. But the FDA -- the RiskMAP 21 requires a supplement, which is a formal 22 application, to make a change, correct?</p> <p>23 MR. DIAMANTATOS: Objection. 24 Form. Foundation.</p>

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<p>1 THE WITNESS: We tried that. 2 I mentioned that, yes. 3 BY MR. CRAWFORD: 4 Q. Right. But I'm just asking, 5 did you try, after this audit, to do that 6 or before this audit to make the change? 7 MR. DIAMANTATOS: Objection. 8 Form. Foundation. Asked and 9 answered. 10 THE WITNESS: I'd have to 11 look at the log. I just don't 12 remember. 13 There was a lot of 14 communication about changes. 15 BY MR. CRAWFORD: 16 Q. All right. Then 8.2.1, it 17 says that, NDC source prescribers was 18 used instead of IMS Xponent. NDC source 19 prescriber data is not reported. We only 20 report that no specialty exceeds 15 21 percent. 22 That was -- that was what we 23 looked at when you flagged it under 24 8.2.1, right?</p>	<p>1 So there is documentation to 2 support all this. I don't think 3 in this -- in this audit report it 4 was evaluated as appropriately 5 as -- maybe as deep as it should 6 have been. 7 Because we have 8 documentation -- just like he 9 could have -- he could have 10 referenced the documentation where 11 we communicated to the FDA what 12 our changes were. 13 That gives you a sense 14 that -- I think this was a first 15 pass, and this should have been a 16 deeper dive, in terms of some of 17 these findings, because there -- 18 there were -- and we actually -- 19 we had follow-up to this case. 20 But there was everything, 21 you know, that we were doing 22 correctly. And we had 23 documentation to support it.</p>
<p>1 A. That's correct. 2 Q. Then -- I mean, just looking 3 through this, he found -- Mr. Brennan did 4 find a number of inconsistencies between 5 the practices of the company in 6 effectuating the RiskMAP and what the 7 RiskMAP required, right? 8 MR. DIAMANTATOS: Objection 9 to form. Foundation. 10 THE WITNESS: So what I 11 explained before is there were 12 inconsistencies against the 13 original one that he looked at. 14 If he -- I used to head up 15 the compliance group. If he did 16 his -- if it was correctly 17 evaluated, he -- what should have 18 happened is he would have gone to 19 look at the actual documentation, 20 which was -- which I saw 21 originally, and it was stored in 22 files. And he could have looked 23 for himself about the 15 percent, 24 as an example.</p>	<p>1 Q. But the RiskMAP requires 2 actual approval by the FDA, through a 3 supplemental process, to make changes; 4 that's mandatory in the RiskMAP, right? 5 MR. DIAMANTATOS: Objection. 6 Form. Asked and answered. 7 THE WITNESS: I mean, I 8 don't know how many times you want 9 me to say it. 10 We did -- we communicated 11 one way. I talked to the FDA 12 project manager. And we had to -- 13 some of these things couldn't 14 feasibly be done, and so what are 15 we supposed to do? 16 You know, if anything, we 17 went -- for instance, there's 18 questions in the RiskMAP that you 19 were supposed to ask on callback. 20 By the time we kept evolving 21 and making this more and more 22 robust, we had pages of questions 23 to ask. So, if anything, if you 24 saw what we really did, it was a</p>
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<p>1 lot more robust than the initial 2 RiskMAP. 3 We added a whole lot of 4 things, but we couldn't get it 5 included. Not only couldn't we 6 get the changes, but we could not 7 get the additional things we 8 added. 9 So, you know, and -- 10 eventually the FDA, we had a 11 meeting with the FDA, we made them 12 aware of everything. We reviewed 13 all the data with them. They had 14 no problem with what we were 15 doing.</p> <p>16 BY MR. CRAWFORD: 17 Q. Okay. They had no problem 18 with any of the practices that you 19 were -- you had in place -- 20 A. That's correct. 21 Q. Hold on. 22 -- the practices that you 23 had in place that didn't conform to the 24 exact terms of the written RiskMAP?</p>	<p>1 look at the date. 2 Q. Let's mark something here. 3 MR. CRAWFORD: 1138. Let's 4 see if this is the binder or 5 information that you're 6 referencing. 7 This is July 12th, 2004. 8 THE WITNESS: That sounds 9 right. 10 MR. CRAWFORD: We'll give 11 you a copy. 12 THE WITNESS: That sounds 13 right. 14 MR. CRAWFORD: Why don't we 15 mark it, and you can just confirm 16 this is the meeting where they 17 said everything was okay. 18 THE WITNESS: I don't want 19 to say -- let me be clear. I 20 didn't say they said everything 21 was okay. We -- I'm sorry if I 22 misrepresented. 23 We presented all the 24 information. They received all</p>
<p>1 MR. DIAMANTATOS: Objection. 2 Form. 3 BY MR. CRAWFORD: 4 Q. Is that what you're saying? 5 A. Yes. We met with them and 6 we went through the whole RiskMAP 7 process, all the data. And we were -- 8 there were no issues. We never got any 9 problem -- any letters. 10 And we had, I don't know, 15 11 people at the FDA in that room who did 12 not have a problem with anything we did. 13 They understood what we were talking 14 about. 15 Q. And when was that meeting? 16 A. I remember it was July. I'd 17 have to look at the date. 18 Q. July of '04, after this 19 report? 20 A. I'm sorry, I'd have to look 21 at the date. But it was -- there's a big 22 binder -- because we went -- we had a 23 huge meeting with the agency. 24 It was -- yeah. I'd have to</p>	<p>1 the documentation. And at the end 2 of that, we've never -- they 3 thanked us for coming, and we 4 never received any negative letter 5 or anything to the fact. 6 - - - 7 (Whereupon, Teva-Marchione 8 Exhibit-11, 9 TEVA_MDL_A_01575289-972, was 10 marked for identification.) 11 - - - 12 BY MR. CRAWFORD: 13 Q. So we marked here 14 Exhibit-11. 15 And this is the meeting that 16 you're referring to that was to occur on 17 July 14th, right, 2004? 18 A. July -- that's correct. 19 Q. We'll get back to this. I 20 just wanted to get our timeline straight. 21 So Mr. Brennan lists here -- 22 let's go to the items requiring follow 23 up, which is on Page 330 here. 24 He's listed 14 points,</p>

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<p>1 right, on those two pages?</p> <p>2 A. Okay. Yep. Yep.</p> <p>3 Q. So one item requiring</p> <p>4 follow-up, he does reference the four</p> <p>5 listed pharmacy chains are not included</p> <p>6 as required by Section 8.1.1.</p> <p>7 Section 8.0 further commits</p> <p>8 that if any of the four organizations</p> <p>9 aren't able to participate, Cephalon will</p> <p>10 substitute another supplier, only</p> <p>11 Walgreens is represented.</p> <p>12 Does that -- does that</p> <p>13 accurately reflect what the situation was</p> <p>14 at that time, that only Walgreens was</p> <p>15 represented?</p> <p>16 MR. DIAMANTATOS: Objection.</p> <p>17 Form. Foundation. Calls for</p> <p>18 speculation.</p> <p>19 THE WITNESS: Yeah, I'd have</p> <p>20 to look. I don't know.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. There are a number of points</p> <p>23 here.</p> <p>24 Number 3, NDC Source</p>	<p>1 BY MR. CRAWFORD:</p> <p>2 Q. It says, This section</p> <p>3 requires that inappropriate prescriptions</p> <p>4 representing potential off-label usage</p> <p>5 greater than 15 percent of the total</p> <p>6 Actiq prescriptions will prompt Cephalon</p> <p>7 to offer educational programs to the</p> <p>8 various professional societies. It is</p> <p>9 further specified -- it further specifies</p> <p>10 that if the potential off-label usage</p> <p>11 greater than 15 percent continues for two</p> <p>12 additional quarters, Cephalon will</p> <p>13 initiate an, quote, aggressive, unquote,</p> <p>14 education campaign. No documentation of</p> <p>15 intervention could be found.</p> <p>16 So that was one of Mr.</p> <p>17 Brennan's findings in this document,</p> <p>18 right?</p> <p>19 MR. DIAMANTATOS: Objection.</p> <p>20 Form. Foundation. Calls for</p> <p>21 speculation.</p> <p>22 Go ahead.</p> <p>23 THE WITNESS: The reason I'm</p> <p>24 hesitating is because I'm not sure</p>
Page 179	Page 181
<p>1 Prescriber is used in place of IMS</p> <p>2 Xponent specified in Section 8.2.1.</p> <p>3 That's another issue he</p> <p>4 raised, correct? I think you address</p> <p>5 that.</p> <p>6 A. It's written here.</p> <p>7 MR. DIAMANTATOS: Objection.</p> <p>8 Form.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Going to Number 12, he says,</p> <p>11 The quarterly RiskMAP or RMP report omits</p> <p>12 Section 9.1.2.</p> <p>13 We saw that in Exhibit-9</p> <p>14 that we looked at, right?</p> <p>15 MR. DIAMANTATOS: Objection</p> <p>16 to form.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. Remember 9.1.2 was missing,</p> <p>19 right?</p> <p>20 MR. DIAMANTATOS: Objection</p> <p>21 to form.</p> <p>22 THE WITNESS: Right. But we</p> <p>23 told you that instead we had it</p> <p>24 addressed earlier.</p>	<p>1 if any did exceed it.</p> <p>2 So he's saying -- and that's</p> <p>3 why I'm reading 13.</p> <p>4 BY MR. CRAWFORD:</p> <p>5 Q. All right. Yes, let's read</p> <p>6 13.</p> <p>7 SOP 0426-J02 indicates that</p> <p>8 only individual specialties with</p> <p>9 prescription rates exceeding 15 percent</p> <p>10 of the total Actiq prescriptions will be</p> <p>11 reported to regulatory affairs. There</p> <p>12 are approximately 85 specialties</p> <p>13 reported, three of which are included in</p> <p>14 the list of exemptions in the SOP. This</p> <p>15 does not comply with the requirement in</p> <p>16 Section 9.1.2 that prescriptions</p> <p>17 representing potential off-label usage</p> <p>18 greater than 15 percent prompts action.</p> <p>19 A. That doesn't make any sense</p> <p>20 to me. Because it doesn't -- it doesn't</p> <p>21 talk about exceeding the 15 percent.</p> <p>22 I don't understand.</p> <p>23 Q. Right. But let's at least</p> <p>24 break down what he's saying.</p>

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<p style="text-align: right;">Page 182</p> <p>1 He says there are 2 approximately 85 specialties reported. 3 So were there about 85 4 specialties that the practice groups were 5 broken into for evaluation of the 15 6 percent threshold?</p> <p>7 MR. DIAMANTATOS: Objection.</p> <p>8 Form. Foundation.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Does that refresh your 11 recollection?</p> <p>12 A. I don't even understand what 13 he's saying.</p> <p>14 MR. DIAMANTATOS: Objection 15 to form. One second. One second.</p> <p>16 THE WITNESS: Sorry.</p> <p>17 MR. DIAMANTATOS: Objection.</p> <p>18 Form. Foundation. The witness 19 never said she can't remember.</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. Do you remember there was a 22 process, I think you referenced a 23 document that you would get, where they 24 broke down the specialties in order to</p>	<p style="text-align: right;">Page 184</p> <p>1 That's the handwritten part 2 at the bottom of Page 331.</p> <p>3 A. That's what it says there.</p> <p>4 Q. And RA, you would assume 5 that's regulatory affairs, right?</p> <p>6 A. But I don't know whose 7 handwriting this is, and, you know.</p> <p>8 Q. Do you recall your 9 department preparing a report, or being 10 asked to, about this time?</p> <p>11 A. I recall having a meeting to 12 discuss these issues. And I'm sure -- I 13 think there was a document to address all 14 the issues. And it's probably in that 15 RMP file I was telling you.</p> <p>16 Q. If you could look at Page 17 345, there appears to be some type of 18 policy, POL-0009. It's marked draft.</p> <p>19 Is this -- can you tell 20 me -- have you seen this document before, 21 and can you tell me what it is?</p> <p>22 A. 345.</p> <p>23 So my recollection is it's a 24 draft SOP on the RiskMAP.</p>
<p style="text-align: right;">Page 183</p> <p>1 assess if any exceeded 15 percent for 2 nontargeted, right?</p> <p>3 A. That's correct.</p> <p>4 Q. Okay. And there were, what, 5 approximately three targeted 6 specialties -- or how many targeted 7 specialties were there?</p> <p>8 MR. DIAMANTATOS: Objection.</p> <p>9 Form.</p> <p>10 THE WITNESS: I don't -- I 11 can't tell from -- this doesn't 12 make sense to me, what he wrote. 13 So I can't tell you what he's 14 trying to say.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Were there -- is he right 17 that there were approximately 85 18 specialties that it was broken down to 19 for the evaluation of the 15 percent?</p> <p>20 A. I just don't remember.</p> <p>21 Q. All right. It says, Action: 22 RA -- that's regulatory affairs, right -- 23 will issue a response audit report by 24 12/31, right?</p>	<p style="text-align: right;">Page 185</p> <p>1 Q. Do you recall if there was a 2 final one at this time, or just the draft 3 that he attaches here?</p> <p>4 A. I don't recall.</p> <p>5 Q. If you turn to the third 6 page of it, Surveillance. Well, 7 actually, go to Section 5, 8 Responsibilities.</p> <p>9 It says, The RMP team 10 includes management representatives from 11 marketing, sales, drug safety and 12 regulatory affairs. This team -- or the 13 team ensures that adequate systems are in 14 place to support the RMP program.</p> <p>15 And then skipping down, it 16 says, Specific areas of responsibility 17 directly relevant to the various RMP 18 sections are assigned below.</p> <p>19 Was that -- even though it 20 says draft, was that kind of the practice 21 at the time with regard to the 22 responsibilities for implementing the 23 program?</p> <p>24 MR. DIAMANTATOS: Objection.</p>

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<p style="text-align: right;">Page 186</p> <p>1 Form.</p> <p>2 THE WITNESS: That's</p> <p>3 correct. Because what the</p> <p>4 activities were fell under the</p> <p>5 operations of different groups.</p> <p>6 BY MR. CRAWFORD:</p> <p>7 Q. Right. And is it accurate</p> <p>8 that marketing, sales, drug safety and</p> <p>9 regulatory affairs all had a hand in</p> <p>10 responsibility for making sure this</p> <p>11 program was put into effect?</p> <p>12 A. To my recollection.</p> <p>13 Q. And you're regulatory</p> <p>14 affairs.</p> <p>15 You were one of several</p> <p>16 departments, right?</p> <p>17 A. That's correct.</p> <p>18 Q. And then below, it looks</p> <p>19 like how they kind of divided up</p> <p>20 responsibility.</p> <p>21 If you could look at 5.1 and</p> <p>22 those assignments, does that basically</p> <p>23 comport to your recollection of how the</p> <p>24 duties were divided up -- or</p>	<p style="text-align: right;">Page 188</p> <p>1 off-label usage, that was drug safety and</p> <p>2 marketing, right?</p> <p>3 MR. DIAMANTATOS: Objection.</p> <p>4 Form.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. That had that</p> <p>7 responsibility?</p> <p>8 That was right under 5.4,</p> <p>9 the second one.</p> <p>10 A. Right. Yes.</p> <p>11 Q. And then right below that,</p> <p>12 marketing had the responsibility for the</p> <p>13 IMS Xponent, IMS NDTI, and promotional</p> <p>14 message audit, right?</p> <p>15 A. That's what -- yes.</p> <p>16 Q. And quality assurance had</p> <p>17 the DEA communications, right?</p> <p>18 A. Correct.</p> <p>19 Q. And then drug safety, the</p> <p>20 abuse and other matters, too, right,</p> <p>21 listed there?</p> <p>22 A. That's correct.</p> <p>23 Q. Sales and marketing, it</p> <p>24 looks like they had the responsibility</p>
<p style="text-align: right;">Page 187</p> <p>1 responsibility was divided up with regard</p> <p>2 to the RiskMAP?</p> <p>3 A. There was a -- there's</p> <p>4 probably another subsection of marketing</p> <p>5 research, because a lot of the things</p> <p>6 came from them, like the IMS database.</p> <p>7 So I guess it is subsumed</p> <p>8 under the marketing group.</p> <p>9 Q. So wouldn't marketing</p> <p>10 research -- weren't they a subset or</p> <p>11 subdepartment of the marketing</p> <p>12 department?</p> <p>13 A. Yeah. But it's -- yes.</p> <p>14 Yes.</p> <p>15 Q. So it looks like here, at</p> <p>16 least for your responsibilities, they</p> <p>17 were, the patient leaflet and package</p> <p>18 insert, right?</p> <p>19 A. That's correct. That's what</p> <p>20 it says here.</p> <p>21 Q. And then the -- skipping</p> <p>22 down, the FDA quarterly reporting, right?</p> <p>23 A. That's correct.</p> <p>24 Q. And then things like</p>	<p style="text-align: right;">Page 189</p> <p>1 for target audience, sales representative</p> <p>2 training and field direction, right?</p> <p>3 A. Again, this is a draft</p> <p>4 document. I don't know if it's evolved.</p> <p>5 And we had other groups.</p> <p>6 But that's what it says in</p> <p>7 this document, yes.</p> <p>8 Q. But this is, if Mr. Brennan</p> <p>9 attached it, this must -- do you agree</p> <p>10 this was the practice at the time, as far</p> <p>11 as dividing up responsibility?</p> <p>12 MR. DIAMANTATOS: Objection.</p> <p>13 Calls for speculation.</p> <p>14 THE WITNESS: Without having</p> <p>15 an approved document, I'm just</p> <p>16 hesitant, because if somebody</p> <p>17 would disagree that that's their</p> <p>18 area, I can't tell you that.</p> <p>19 So if somebody drafts</p> <p>20 something, people may not agree to</p> <p>21 it. So you have it in front of</p> <p>22 you, but it may not be accurate.</p> <p>23 It seems correct to me, but</p> <p>24 I'm sure somebody could have a</p>

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<p style="text-align: right;">Page 190</p> <p>1 difference of opinion. 2 BY MR. CRAWFORD: 3 Q. Fair enough. 4 So it does say below that, 5 POL-0009, draft, it says, Change, new 6 policy. 7 So it looks like it's 8 something that people were trying to get 9 down in writing at the time, right? 10 MR. DIAMANTATOS: Objection 11 to form. Calls for speculation. 12 THE WITNESS: That's my 13 recollection. 14 BY MR. CRAWFORD: 15 Q. But you -- putting the 16 report together, you needed to get input 17 from all these different departments 18 about their responsibility so you could 19 report it accurately to the FDA, right? 20 A. That's correct. 21 Q. And I'm just asking for your 22 understanding, not what other people may 23 have thought was their responsibility. 24 Your understanding was this</p>	<p style="text-align: right;">Page 192</p> <p>1 who was on the org chart we looked at, 2 right? 3 A. That's correct. 4 Q. And then there are other 5 people here from sales and marketing. 6 Andy Pyfer is one of the 7 recipients, was he in marketing? 8 A. Yes, yes. 9 Q. And then a cc to David 10 Brennan, right? He's the guy that 11 prepared the audit? 12 A. That's correct. 13 Q. It's dated December 15th, 14 2003, Re: Actions to respond to audit 15 findings regarding the Actiq risk 16 management program, quality assurance 17 memorandum, 12/2/03. 18 Do you recall receiving -- 19 or preparing this memo? 20 A. No. No, actually, I don't. 21 Q. And if you look at the next 22 page, it looks like these are the 14 23 points that Mr. Brennan had raised in his 24 audit report.</p>
<p style="text-align: right;">Page 191</p> <p>1 is how the responsibilities broke down 2 and who would report to you on each one, 3 right? 4 A. What I can remember. 5 Q. Thank you. 6 MR. JENSEN: Exhibit-12. 7 - - - 8 (Whereupon, Teva-Marchione 9 Exhibit-12, TEVA_MDL_A_011595-553, 10 was marked for identification.) 11 - - - 12 MR. CRAWFORD: That's 13 Document 554. 14 BY MR. CRAWFORD: 15 Q. All right. We've marked 16 here TEVA_MDL_A_011595, a memo from you, 17 Carol Marchione, to certain people, Paul 18 Blake. 19 Who -- was he your boss at 20 the time? 21 A. I believe, because Victor 22 must have been on board by that time, so 23 he was my boss's boss. 24 Q. I see. Victor Raczkowski,</p>	<p style="text-align: right;">Page 193</p> <p>1 Do those look familiar? And 2 then at least some kind of response, 3 right, by the company? 4 MR. DIAMANTATOS: Objection 5 to form. 6 THE WITNESS: I'd have to 7 review it. It doesn't -- it does 8 not look familiar to me. 9 It seems that way. 10 BY MR. CRAWFORD: 11 Q. Okay. Take a look at 12 Exhibit -- 13 MR. CRAWFORD: Was it 10? 14 MR. JENSEN: Yes, 10. 15 BY MR. CRAWFORD: 16 Q. Take a look at Exhibit-10. 17 A. Exhibit-10. 18 Q. Yes. Take a look at 19 Exhibit-10. 20 It attached 14 points -- 21 A. I'm sorry, what's 22 Exhibit-10? Is that the -- 23 Q. The Brennan report. 24 A. Okay.</p>

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<p style="text-align: center;">Page 194</p> <p>1 Q. Those are the same 14 points 2 that he had put in his audit report of 3 12/2/03, right? 4 And then this is at least 5 some type of response to each point below 6 it, right? 7 A. It appears that way. 8 Q. And, I mean, do you recall 9 anything about putting this memo 10 together? 11 And take some time to look 12 at it if you want to. 13 A. Actually, I don't. It could 14 have been initially put together by 15 Tracie Parker, who worked for me. 16 So is there a particular -- 17 what do you want me to read? Is there -- 18 Q. Yes. Okay. I'll direct you 19 in a second here. 20 But this would have been -- 21 if somebody prepared something for your 22 signature, you would have read it? 23 A. Definitely. 24 Q. Definitely, okay.</p>	<p style="text-align: center;">Page 196</p> <p>1 Q. Do you recall that meeting 2 at all? Is that refreshing your 3 recollection? 4 A. I believe there was a 5 meeting to talk about this afterwards, I 6 do. 7 Q. It says, Additionally, a 8 meeting with sales and marketing needs to 9 be convened to discuss their 10 understanding of the, quote, 11 inappropriate, unquote, physician 12 specialties to be monitored for the 15 13 percent limit, Items 12 and 13. Due to 14 the additional activity, it was estimated 15 that a memo to respond to the audit 16 finding would be issued by year end. 17 Subsequently a revised RMP 18 containing any necessary revisions will 19 be issued by the end of January 2004 for 20 review by the management of the various 21 departments impacted by the RMP. 22 So do you interpret the 23 intent here as to looking at Mr. 24 Brennan's points and providing a revised</p>
<p style="text-align: center;">Page 195</p> <p>1 So when you're on -- you 2 have no reason to doubt that this isn't a 3 record from -- from the -- from your 4 regulatory files, right? 5 A. That's correct. 6 Q. Okay. And you would have -- 7 if somebody else helped prepare it for 8 you, you would have read it and verified 9 that you agreed with it, right? 10 A. That's correct. 11 Q. So I just want to direct 12 your attention here, I guess, to the 13 comments on the first page. 14 The memo states, In response 15 to the audit findings outlined in the 16 quality assurance memorandum regarding 17 the Actiq risk management program, RMP, 18 representatives from quality assurance, 19 global product safety, marketing, legal, 20 and regulatory affairs met on December 21 11th to review the 14 items requiring 22 follow up. 23 Do you see that? 24 A. Yes.</p>	<p style="text-align: center;">Page 197</p> <p>1 RMP based on the points that he had 2 raised? 3 MR. DIAMANTATOS: Objection 4 to form. 5 THE WITNESS: That's how I 6 would interpret this. BY MR. CRAWFORD: 8 Q. And do you know if, in fact, 9 a revised RMP was prepared subsequent to 10 this memo, for the Actiq risk management 11 program? 12 A. I can't remember. But it 13 would be in our log. 14 Q. Do you recall, you, 15 yourself, putting one together, a revised 16 RMP? 17 A. I have hundreds of 18 submissions that I put together. So, I'm 19 sorry, I'd have to look at the log. 20 Q. Understood. Thank you. All 21 right. 22 It says, below that, Post -- 23 updated, post-meeting note: Legal (Ed 24 Berg) met with sales following the 12/11</p>

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<p style="text-align: center;">Page 198</p> <p>1 meeting and determined that the required 2 concepts of Number 9 are being met 3 through a regular sales department 4 process. And, further, that Item 13 is 5 adequately outlined in SOP 0426-J02. 6 This information will be reflected in the 7 year-end memorandum noted.</p> <p>8 So, basically, the 9 determination was made with these groups 10 that met, which included all these 11 groups, that the existing SOP adequately 12 addressed the 15 percent issue, right?</p> <p>13 A. I mean, that's what it says here.</p> <p>15 At this point, I think, 16 following this audit, our legal group 17 took over kind of the oversight, more 18 than myself, of everything coming from 19 our sales and marketing. And that's Ed 20 Berg's reference. So, I mean, that's 21 what this is saying.</p> <p>22 Q. All right. But it's also 23 saying that the SOP, in their view, 24 looked adequate to address the issue?</p>	<p style="text-align: center;">Page 200</p> <p>1 A. Yes, he was. 2 Q. It looks like Mr. Berg has 3 some other responsibilities with regard 4 to these points, including Point 10, it 5 looks like somebody wrote, Ed Berg? 6 A. Yeah, that's not my document. 8 Q. That's not your handwriting 9 here? 10 A. No. 11 Q. Let's go to -- 12 MR. CRAWFORD: How we doing? 13 Do you want to keep going here or 14 take a short break for lunch? How 15 do you feel? 16 MR. DIAMANTATOS: Why don't 17 we take a lunch break? 18 THE WITNESS: Yes, let's 19 take a lunch break. 20 VIDEO TECHNICIAN: Going off 21 the record at 12:39 p.m. 22 - - - 23 (Whereupon, a luncheon 24 recess was taken.)</p>
<p style="text-align: center;">Page 199</p> <p>1 A. That's -- what you read is 2 what it says. 3 Q. Take a look at Number 13. 4 Actually, it does say, We respectively 5 request to defer our response to this 6 follow-up item. An internal meeting 7 should be convened to discuss how the 8 pain specialists are determined. 9 So at this point, at least, 10 there was no official response to the 13 11 -- it looks like there was going to be a 12 follow-up discussion about it, right? 13 A. What I mentioned to you is 14 then, from that point, our legal 15 representatives took over that point and 16 that process. 17 So I think I was out of the 18 loop at that point. So that's -- that's 19 as far as I could respond to it. 20 Q. And that was Mr. Berg, then, 21 right? 22 A. It was, yes. 23 Q. And he was in the legal 24 department?</p>	<p style="text-align: center;">Page 201</p> <p>1 - - - 2 VIDEO TECHNICIAN: Back on 3 the record at 1:13 p.m. 4 BY MR. CRAWFORD: 5 Q. We have since, during the 6 lunch break, retrieved a document that 7 appears to be the 1999 RiskMAP, which we 8 had referenced earlier. 9 I think that -- we were 10 looking at Exhibit-7, which is the August 11 1st, 2001 RiskMAP listing Anesta Corp, a 12 subsidiary of Cephalon. And I think 13 we've been operating off of that. 14 But you thought that 15 possibly, I think, correct me if I'm 16 wrong, that there was an earlier RiskMAP 17 that may have been the actual operative 18 one from '99. 19 And so we've attached 20 Exhibit-8, kind of a large, full 21 document, but with a copy of a Page 7857. 22 This is document TEVA_MDL_A_08387849. At 23 Page 7857 is what appears to be a 24 February 9th, 1999 RiskMAP.</p>

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<p style="text-align: center;">Page 202</p> <p>1 - - -</p> <p>2 (Whereupon, Teva-Marchione</p> <p>3 Exhibit-8,</p> <p>4 TEVA_MDL_A_08387849-8059, was</p> <p>5 marked for identification.)</p> <p>6 - - -</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. And I just want to ask you</p> <p>9 if this refreshes your recollection that</p> <p>10 that's the '99 RiskMAP that you were</p> <p>11 thinking of?</p> <p>12 A. It may be. I'd have to look</p> <p>13 word by word. I didn't submit this.</p> <p>14 And I don't know if there</p> <p>15 was FDA changes to it. So I really can't</p> <p>16 say for sure.</p> <p>17 Q. Yeah. But you had thought,</p> <p>18 possibly, that the effective one that ran</p> <p>19 through all the time you were there was</p> <p>20 the '99 RiskMAP, not the '01, which you</p> <p>21 thought may have had some adjustments to</p> <p>22 it that hadn't been approved by the FDA;</p> <p>23 is that correct?</p> <p>24 MR. DIAMANTATOS: Objection.</p>	<p style="text-align: center;">Page 204</p> <p>1 NDA is dynamic, so it's not -- it's a</p> <p>2 living document. So there's nothing</p> <p>3 that's necessarily in time, unless it</p> <p>4 says it's approved.</p> <p>5 So the FDA said -- if in the</p> <p>6 approval letter it says, your RiskMAP as</p> <p>7 of February 19th, that submission, is</p> <p>8 approved, that's the only way I could</p> <p>9 tell.</p> <p>10 Q. That's very clear. Thank</p> <p>11 you.</p> <p>12 But, anyway, there is a '99</p> <p>13 RiskMAP here. If we found an FDA letter</p> <p>14 that approved this one submitted here,</p> <p>15 that would give you some assurance that</p> <p>16 this is the one, the '99 one, that was in</p> <p>17 effect when you arrived, right?</p> <p>18 MR. DIAMANTATOS: Objection</p> <p>19 to form.</p> <p>20 Go ahead.</p> <p>21 THE WITNESS: It appears</p> <p>22 that way, but I'd have to go word</p> <p>23 by word.</p> <p>24 BY MR. CRAWFORD:</p>
<p style="text-align: center;">Page 203</p> <p>1 Form.</p> <p>2 Go ahead.</p> <p>3 THE WITNESS: So the way it</p> <p>4 works is they submit it -- you'd</p> <p>5 have to see the correspondence</p> <p>6 back-and-forth with the FDA.</p> <p>7 Because I was thinking about</p> <p>8 looking at the approval letter,</p> <p>9 because sometimes they'll</p> <p>10 reference the date of the</p> <p>11 submission for the RiskMAP.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. Who is "they"?</p> <p>14 A. FDA.</p> <p>15 So this is considered --</p> <p>16 until I know that FDA said, this is</p> <p>17 approved, this is just a draft,</p> <p>18 basically.</p> <p>19 Q. Right.</p> <p>20 A. So I don't know if the</p> <p>21 approval letter referenced this as the</p> <p>22 RiskMAP or if there was correspondence in</p> <p>23 between.</p> <p>24 You know, anything to the</p>	<p style="text-align: center;">Page 205</p> <p>1 Q. And also see -- yeah, see</p> <p>2 the sequence resulting in an FDA approval</p> <p>3 letter, right?</p> <p>4 A. That's correct.</p> <p>5 Q. So it does say on this</p> <p>6 letter, February 10th, 1999, from Anesta,</p> <p>7 Reference is made to the November 4th,</p> <p>8 1998 approval letter for the Actiq NDA.</p> <p>9 Specific reference is made to your</p> <p>10 comments concerning any proposed changes</p> <p>11 to the current risk management program,</p> <p>12 RMP, which is dated November 4th, 1998.</p> <p>13 Since the RMP is considered an integral</p> <p>14 part of the approved NDA, we draw your</p> <p>15 attention to the revised RMP included in</p> <p>16 this submission. We trust that it will</p> <p>17 meet with your approval.</p> <p>18 So they are seeking --</p> <p>19 you're interpreting this as they're</p> <p>20 submitting this attached RiskMAP for the</p> <p>21 FDA approval with any changes they had?</p> <p>22 A. Right. And you don't --</p> <p>23 MR. DIAMANTATOS: Objection.</p> <p>24 Form. Foundation. Calls for</p>

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<p style="text-align: right;">Page 206</p> <p>1 speculation. 2 Go ahead. 3 THE WITNESS: And you don't 4 know that without seeing 5 correspondence from the FDA. 6 BY MR. CRAWFORD: 7 Q. We'll look for that. 8 I think -- I think -- my 9 recollection, I want to see if this may 10 be your recollection, if you went back 11 and reviewed these, I know you weren't 12 here at the time, but I think they 13 dropped Abbott as a marketing partner at 14 this time, and that may have been the 15 change that they requested. 16 Does that refresh your 17 recollection? 18 A. That sounds -- that 19 sounds -- I know there was a situation 20 about dropping Abbott. I just don't know 21 if there were any other changes to it. 22 I don't think there was 23 anything substantive. But, again, there 24 may be some operational things. I just</p>	<p style="text-align: right;">Page 208</p> <p>1 Does that look like what 2 could be the approved, original RiskMAP? 3 MR. DIAMANTATOS: Objection. 4 Form. Foundation. Calls for 5 speculation. 6 THE WITNESS: I'm just -- 7 I'm seeing what you're seeing. 8 It looks like this is FDA 9 approved RMP November 4, 1998. So 10 I'm assuming this is the first. 11 I'm assuming there was a revised 12 one of February 9th, 1999. 13 And what date is this? 14 BY MR. CRAWFORD: 15 Q. That they submitted with 16 this packet, right? 17 A. Right. 18 But I don't know if it was 19 ever approved. 20 Q. And the missing link is 21 finding whether there was an approval 22 letter of this particular one, right? 23 A. Correct. 24 Q. If we found it, that would</p>
<p style="text-align: right;">Page 207</p> <p>1 don't know, without looking at it word by 2 word. 3 Q. Okay. Sounds like we have a 4 missing piece there. 5 It looks like, if you look 6 at Page 7855, that this packet does 7 attach an FDA-approved RMP dated November 8 4th, 1998, at Page 19-124, which was the 9 original RiskMAP. 10 Would that be how you would 11 understand this document? 12 A. Yes, that's how I would 13 understand that. 14 Q. And, in fact, when you go to 15 Page 124 -- or, actually, 125 -- well, 16 let's see. 17 124 says, FDA approved RMP, 18 November 4th, 1998. Note: The attached 19 RMP was included in the November 4th, 20 1998 facsimile from FDA. See November 4, 21 1998 approval letter. 22 And then the next page is 23 the risk management program, November 24 4th, 1998.</p>	<p style="text-align: right;">Page 209</p> <p>1 give you some assurance that this, in 2 fact, was the one in operation, at least 3 on the date of approval? 4 A. They -- likewise, they may 5 have -- if I remember correctly, they may 6 have said the same thing, that we 7 submitted -- there may not be an approval 8 letter, is what I'm trying to say. I 9 don't know if the FDA came back and 10 approved it. 11 Q. All right. Let's go to the 12 next document. This is 1140. 13 MR. JENSEN: Exhibit-13. 14 - - - 15 (Whereupon, Teva-Marchione 16 Exhibit-13, 17 TEVA_MDL_A_08531805-810, was 18 marked for identification.) 19 - - - 20 BY MR. CRAWFORD: 21 Q. So here we marked as 22 document TEVA_MDL_A_08531805, Exhibit-13. 23 It looks like a standard 24 operating procedure, SOP-0001053, dated</p>

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<p style="text-align: right;">Page 210</p> <p>1 February 11, 2005. 2 And the SOP is called, 3 Marketing Support of the Actiq Risk 4 Management Program. And approvals are 5 noted here, including your name, of 6 February 11th, 2005. 7 Do you recall being involved 8 in approving this particular SOP about 9 the marketing support of Actiq risk 10 management program? 11 A. I actually don't remember. 12 Q. But your name is on here. 13 And do you have any reason 14 to doubt that this is the approved 15 program and that you had -- at least had 16 a hand in the approval?</p> <p>17 MR. DIAMANTATOS: Objection. 18 Form. 19 Go ahead.</p> <p>20 THE WITNESS: I can only 21 assume that I -- you know, but I 22 just don't remember. But it says 23 here that I approved, so I'm 24 assuming that the database copied</p>	<p style="text-align: right;">Page 212</p> <p>1 Paragraph 1, or the top, says, Purpose 2 and scope: The procedure outlines 3 marketing's responsibilities for the 4 Actiq risk management program, RMP, and 5 NDA approval letter. The intent of the 6 risk management plan is to support the 7 approval of Actiq and to assure patient 8 access while addressing the potential 9 risks associated with appropriate patient 10 selection, child safety, diversion and 11 abuse. 12 And it does say, Departments 13 affected, marketing, sales, global 14 product safety, regulatory affairs and 15 legal. 16 So do you interpret this or 17 understand this document to be an SOP, a 18 standard operating procedure, 19 encompassing marketing's responsibility 20 with regard to the Actiq risk management 21 program? 22 A. That's what the document 23 says. 24 Q. And is that your</p>
<p style="text-align: right;">Page 211</p> <p>1 that. 2 BY MR. CRAWFORD: 3 Q. So in the regular course of 4 business, if -- you've been involved in 5 getting SOPs approved there at Cephalon, 6 right? 7 MR. DIAMANTATOS: Objection. 8 Form. 9 THE WITNESS: In some cases 10 I've approved SOPs, yes. 11 BY MR. CRAWFORD: 12 Q. So, and then this -- and 13 would this be the normal format that you 14 would see after an approved SOP came out, 15 with the approvals and the attachment 16 document? 17 MR. DIAMANTATOS: Objection 18 to form. 19 THE WITNESS: So we switched 20 over to an electronic system. So 21 I may have never looked at it this 22 way. 23 BY MR. CRAWFORD: 24 Q. All right. Okay. So</p>	<p style="text-align: right;">Page 213</p> <p>1 understanding of what this is? 2 A. Yes, that's my 3 understanding. 4 Q. And there is a section 5 called, Groups of Prescribers, 4.5. 6 And at this point in time, 7 you're still writing the quarterly 8 reports reporting to the FDA on the Actiq 9 risk management program, right? 10 A. Yes. 11 Q. And one of the sections of 12 the RiskMAP is 9.1.2 that we've gone over 13 regarding groups of prescribers and 14 when -- when a group goes above 15 15 percent of Actiq use, that certain 16 actions are to be taken with regard to 17 education of that group through a 18 professional society, right? 19 MR. DIAMANTATOS: Objection 20 to form. 21 THE WITNESS: Yep, that's 22 correct. 23 MR. DIAMANTATOS: 24 Mischaracterizes the exhibit.</p>

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<p style="text-align: right;">Page 214</p> <p>1 Go ahead.</p> <p>2 THE WITNESS: I'm sorry,</p> <p>3 could you repeat the question?</p> <p>4 BY MR. CRAWFORD:</p> <p>5 Q. All right. One of the</p> <p>6 sections of the RiskMAP is 9.1.2, that</p> <p>7 we've gone over, regarding groups of</p> <p>8 prescribers, and when a group goes above</p> <p>9 15 percent of Actiq use, that certain</p> <p>10 actions are to be taken with regard to</p> <p>11 education of that group through a</p> <p>12 professional society, right?</p> <p>13 MR. DIAMANTATOS: Same</p> <p>14 objections.</p> <p>15 THE WITNESS: Nontargeted</p> <p>16 groups, right.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. Right. Nontargeted groups.</p> <p>19 And that's found in</p> <p>20 Exhibit-7, if you wanted to confirm that,</p> <p>21 on Page 27.</p> <p>22 So what I want to do is just</p> <p>23 go through this section and see if you</p> <p>24 can maybe give your understanding of how</p>	<p style="text-align: right;">Page 216</p> <p>1 A. Yes.</p> <p>2 Q. Okay. Do you recall that</p> <p>3 being the process back then?</p> <p>4 MR. DIAMANTATOS: Objection</p> <p>5 to form.</p> <p>6 THE WITNESS: Yes.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. Okay. If needed, a letter</p> <p>9 outlining prescribing concerns and the</p> <p>10 offer to conduct an educational program,</p> <p>11 in conjunction with a professional</p> <p>12 society meeting or other national</p> <p>13 setting, to the applicable professional</p> <p>14 organization (e.g., American College of</p> <p>15 Surgeons, American Academy of Physical</p> <p>16 Medicine and Rehabilitation) is drafted</p> <p>17 and circulated by marketing.</p> <p>18 Upon acceptance of the</p> <p>19 reviewing departments (legal, regulatory</p> <p>20 affairs, global product safety, and</p> <p>21 marketing) this letter will be sent to</p> <p>22 the applicable organization. Responses</p> <p>23 received from the professional</p> <p>24 organization are filed with the letter.</p>
<p style="text-align: right;">Page 215</p> <p>1 the process was to apply with regard to</p> <p>2 targeted and nontargeted groups.</p> <p>3 It says, The Actiq RMP</p> <p>4 Section 9.1.2 requires intervention for</p> <p>5 suspected off-label use in major</p> <p>6 physician group populations. The</p> <p>7 three-digit diagnosis code data is</p> <p>8 evaluated by market research each</p> <p>9 quarter. Any physician specialty</p> <p>10 category, other than those related to</p> <p>11 oncology, hematology or pain specialists</p> <p>12 (including pain medicine, anesthesiology,</p> <p>13 anesthesiology pain medicine, physical</p> <p>14 medicine and rehabilitation and</p> <p>15 palliative medicine), exceeding 15</p> <p>16 percent of total mentions is highlighted.</p> <p>17 The highlighted report is reviewed by</p> <p>18 representatives from global product</p> <p>19 safety, regulatory affairs, sales and</p> <p>20 marketing. If needed, a letter</p> <p>21 concerning -- in other words, regulatory</p> <p>22 affairs, that's you, your department</p> <p>23 would review the highlighted report,</p> <p>24 right?</p>	<p style="text-align: right;">Page 217</p> <p>1 Regulatory affairs includes a copy of</p> <p>2 this correspondence in the quarterly</p> <p>3 report to the FDA.</p> <p>4 So any letter that goes out</p> <p>5 is supposed to be included in the</p> <p>6 quarterly report, right?</p> <p>7 A. That's what it says here.</p> <p>8 Q. And that's your letter you</p> <p>9 send, right?</p> <p>10 A. No, I don't send it. I send</p> <p>11 it to the FDA, but I don't send it out.</p> <p>12 Q. All right. Well, you</p> <p>13 author -- you're the signatory of the</p> <p>14 quarterly report, right?</p> <p>15 A. Of the report, yes.</p> <p>16 Q. Right. And that gets sent</p> <p>17 to the FDA?</p> <p>18 A. That's correct.</p> <p>19 Q. And that's what they're</p> <p>20 referring to here, right, the quarterly</p> <p>21 report?</p> <p>22 MR. DIAMANTATOS: Objection</p> <p>23 to form. Foundation. Calls for</p> <p>24 speculation.</p>

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<p style="text-align: right;">Page 218</p> <p>1 THE WITNESS: I 2 misunderstood. I thought you 3 meant the correspondence. 4 BY MR. CRAWFORD: 5 Q. No, no, not the 6 correspondence to the doctor. 7 But the report reporting on 8 it, you were the author of that? 9 A. That's correct. 10 Q. Program compliance is the 11 responsibility of the Actiq brand leader. 12 So what program, do you 13 know, this SOP that you signed off on, 14 what program are they referring to? 15 MR. DIAMANTATOS: Objection 16 to form. 17 THE WITNESS: I'm sorry, 18 what are you talking about? 19 Program? 20 BY MR. CRAWFORD: 21 Q. The last sentence says, 22 Program compliance is the responsibility 23 of the Actiq brand leader. 24 I'm just wondering what</p>	<p style="text-align: right;">Page 220</p> <p>1 can't -- I don't know all the specific 2 groups. It's in categories -- it's 3 general categories here. 4 Q. Well, it says, Any physician 5 specialty category other than those 6 related to oncology, hematology or pain 7 specialists. 8 And pain specialists include 9 pain medicine, anesthesiology, 10 anesthesiology pain medicine, and 11 physical medicine, rehabilitation and 12 palliative medicine. 13 Those groups are basically 14 exempted out; you don't do any 15 examination, under this procedure, 16 whether those groups are prescribing off 17 label in a manner where the total 18 prescriptions in that group exceed 15 19 percent of the Actiq -- 20 A. So that's the targeted 21 group. 22 Q. Right. 23 A. So this is basically saying 24 the same thing as the RiskMAP, it's the</p>
<p style="text-align: right;">Page 219</p> <p>1 program this refers to. 2 A. I didn't -- I didn't write 3 this, but I'm assuming they mean the 4 compliance to doing these activities. 5 Q. Got it. 6 So that would be the Actiq 7 brand leader, that's the marketing 8 department, right? 9 A. That's my interpretation. 10 Q. And do you know who the 11 Actiq brand leader was at this time? 12 A. I don't remember. It could 13 be Andy Pyfer or Michael Richardson. I'm 14 not sure which. 15 Q. All right. Now, so it looks 16 like to me, and I just want to confirm 17 that this is right, that certain 18 specialties are exempted from this 15 19 percent requirement, examining it, right? 20 A. That's what it says here. 21 Q. And that would be which 22 groups? 23 A. Well, you read it. So 24 it's -- this says including, so I</p>	<p style="text-align: right;">Page 221</p> <p>1 nontargeted group which then exceeds 15 2 percent. 3 Q. Well, the RiskMAP mentions 4 nothing about targeted or nontargeted 5 groups, right? 6 A. I thought it did. 7 Q. Take a look at 9.1.2. 8 This is Cephalon's way of 9 implementing it, but it really doesn't 10 talk about exempting out targeted groups 11 or anything like that, does it? 12 That's exhibit -- you pulled 13 it out there, Exhibit-7, Page 27, at the 14 bottom. 15 I'll just read it for the 16 record. It says, If groups of physicians 17 such as a particular specialty are 18 identified as having prescribed Actiq 19 inappropriately, and those prescriptions 20 represent the potential off-label use 21 greater than 15 percent of total Actiq 22 prescriptions, Cephalon Inc. will contact 23 the appropriate professional society 24 (i.e., American College of Surgeons,</p>

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<p style="text-align: center;">Page 222</p> <p>1 American Society of Anesthesiologists).</p> <p>2 That's the language in the</p> <p>3 RiskMAP, right?</p> <p>4 A. Just give me one minute,</p> <p>5 please.</p> <p>6 Q. Page 27.</p> <p>7 A. No, I know what it says on</p> <p>8 27. But, remember, we combined it.</p> <p>9 So I just want to -- we were</p> <p>10 talking about targeted earlier. That</p> <p>11 word was used in some document.</p> <p>12 Q. 8.2.1 is what you're talking</p> <p>13 about?</p> <p>14 A. 8.2.1? Maybe it was in the</p> <p>15 report.</p> <p>16 So what I explained before</p> <p>17 is that there's targeted groups and</p> <p>18 nontargeted groups. So they identified</p> <p>19 the target groups where they feel that</p> <p>20 cancer patients go to see their</p> <p>21 physician, it may not necessarily be</p> <p>22 oncologists, it could be others. And I</p> <p>23 think that's what's included in this</p> <p>24 general list here of pain meds,</p>	<p style="text-align: center;">Page 224</p> <p>1 nontargeted group, if total Actiq</p> <p>2 prescriptions exceeded 15 percent, then</p> <p>3 that would trigger the -- 15 percent off</p> <p>4 label, then that would trigger the</p> <p>5 duty --</p> <p>6 A. That's my --</p> <p>7 MR. DIAMANTATOS: Objection</p> <p>8 to form.</p> <p>9 THE WITNESS: --</p> <p>10 understanding.</p> <p>11 MR. DIAMANTATOS: Objection</p> <p>12 to form. Foundation.</p> <p>13 Go ahead.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. -- the duty to approach a</p> <p>16 professional society?</p> <p>17 MR. DIAMANTATOS: Same</p> <p>18 objections.</p> <p>19 THE WITNESS: That was my</p> <p>20 understanding.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. Okay. And those are the</p> <p>23 nontargeted groups, right?</p> <p>24 A. So -- yes. Yes.</p>
<p style="text-align: center;">Page 223</p> <p>1 anesthesiologists, anesthesiology pain</p> <p>2 med, physical med, rehab and palliative</p> <p>3 care. So they must have done some</p> <p>4 analysis and said, cancer patients go to</p> <p>5 these doctors.</p> <p>6 So what they're saying is</p> <p>7 that if there's any physician groups that</p> <p>8 don't fall in that general umbrella, if</p> <p>9 they go outside -- if they prescribe over</p> <p>10 15 percent of the total, then that is the</p> <p>11 targeted group, I think we referred to</p> <p>12 that earlier, and that, then -- that they</p> <p>13 would go and go to the group -- you know,</p> <p>14 whatever, I'm making this up, but let's</p> <p>15 say it's psychiatrists, and they would go</p> <p>16 to the psychiatry -- you know, American</p> <p>17 Association of Psychiatry and try to</p> <p>18 say -- you know, let them know that we</p> <p>19 want the list of your doctors to let them</p> <p>20 know about Actiq and how it should be</p> <p>21 used.</p> <p>22 Q. So --</p> <p>23 A. That's my interpretation.</p> <p>24 Q. So if psychiatry, as a</p>	<p style="text-align: center;">Page 225</p> <p>1 Q. So the targeted groups, they</p> <p>2 are targeted groups because they are</p> <p>3 appropriate targets for detailing, right?</p> <p>4 MR. DIAMANTATOS: Objection.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. Is that why they're called</p> <p>7 targeted?</p> <p>8 MR. DIAMANTATOS: Objection.</p> <p>9 Form. Speculation. Foundation.</p> <p>10 THE WITNESS: That was my</p> <p>11 interpretation.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. Okay. So if you're in a</p> <p>14 targeted group, say, these pain</p> <p>15 specialists, anesthesiologists, et</p> <p>16 cetera, there's no analysis that's done</p> <p>17 by the company, under the SOP, whether --</p> <p>18 what percentage of doctors within those</p> <p>19 targeted specialties prescribe Actiq off</p> <p>20 label to see if that total amount</p> <p>21 potentially exceeds 15 percent of the</p> <p>22 total Actiq prescriptions, right?</p> <p>23 MR. DIAMANTATOS: Objection</p> <p>24 to form. Foundation.</p>

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<p style="text-align: right;">Page 226</p> <p>1 THE WITNESS: My 2 interpretation -- my read of the 3 RiskMAP is that there was no -- 4 there was no requirement for that. 5 I don't know if they did analysis 6 on that.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. But, again, the RiskMAP 9 doesn't -- basically, it does say that 10 one of the potential societies you would 11 go to is the American Society of 12 Anesthesiologists, if their total 13 off-label prescribing exceeds 15 percent. 14 So the FDA, or the RiskMAP, 15 at least, contemplates that you might go 16 to the anesthesiologists if their 17 prescribing is over 15 percent off label, 18 right?</p> <p>19 MR. DIAMANTATOS: Objection. 20 Form. Foundation. Calls for 21 speculation. Asked and answered.</p> <p>22 THE WITNESS: I think at the 23 time there may have been -- the 24 FDA interpreted that you wouldn't</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. You were just simply 2 reporting the results to the FDA, as they 3 filtered up from sales and marketing? 4 A. I mean, I would have 5 questioned if, again, gynecology was on 6 there or something. 7 But I just -- or some 8 unusual group. But I didn't go into the 9 details of how they determined that. 10 Q. But your understanding of 11 the process was if they are in a targeted 12 group, like these oncologists, 13 hematologists and pain specialists, they 14 were set aside, no analysis was done of 15 their off-label marketing -- 16 MR. DIAMANTATOS: Objection. 17 BY MR. CRAWFORD: 18 Q. -- as a group? 19 MR. DIAMANTATOS: Objection. 20 Asked and answered. Repeatedly. 21 The same question, the same 22 answers, repeatedly. 23 THE WITNESS: I think that's 24 as far as I can take it.</p>
<p style="text-align: right;">Page 227</p> <p>1 go to an anesthesiologist if you 2 were a cancer patient. 3 And I don't know how -- to 4 be honest, I don't know how they 5 determined the targeted versus 6 nontargeted. It's a commercial 7 question.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Right. So that -- again, 10 this looks like it's in the sales and 11 marketing world, because that's what this 12 SOP applies to, right?</p> <p>13 So you relied on sales and 14 marketing to make a determination of what 15 the targets were and nontargeted groups?</p> <p>16 A. I know that our legal group, 17 then, worked more closely with sales and 18 marketing to work with them to understand 19 their practices.</p> <p>20 Q. But you, in regulatory 21 affairs, were not in charge of trying to 22 figure out who is targeted or nontargeted 23 or how to divide this up?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 229</p> <p>1 I mean, I can't tell you 2 anything else, because I -- you 3 know, there was -- there must 4 have -- you know, I believe our 5 legal group evaluated how they 6 were determining that, because it 7 was raised at the audit. 8 So at that point -- 9 BY MR. CRAWFORD: 10 Q. I'm not asking how it's 11 determined -- I'm sorry to interrupt -- 12 how you determined which groups are the 13 targeted groups. 14 I'm just saying, once 15 they've listed the targeted groups here, 16 they never did -- for the purposes of 17 9.2.1 -- or 9.1.2, they never -- they set 18 those aside and didn't do an analysis, 19 within those groups, of what percentage 20 or what off-label marketing or 21 prescriptions was done, right? 22 MR. DIAMANTATOS: Objection. 23 Form. Vague. Foundation. Calls 24 for speculation. Asked and</p>

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<p style="text-align: right;">Page 230</p> <p>1 answered. 2 THE WITNESS: I don't know. 3 It was done within commercial, so 4 I don't -- I can't answer that. 5 BY MR. CRAWFORD: 6 Q. Well, I'm just trying to see 7 what your interpretation -- I mean, you 8 have -- you have responsibility of 9 reporting on this provision to the FDA. 10 So it just says that any 11 physician specialty category, other than 12 those related to oncology, hematology or 13 pain specialists, that exceed the 15 14 percent of total mentions is highlighted. 15 So it looks like that they 16 have excepted out those targeted groups 17 from the 15 percent analysis, right? 18 MR. DIAMANTATOS: Objection. 19 Form. Foundation. Calls for 20 speculation. Asked and answered 21 multiple times. 22 THE WITNESS: That's my 23 interpretation. And, you know, 24 they -- that's my interpretation.</p>	<p style="text-align: right;">Page 232</p> <p>1 relevant data regarding the Actiq RiskMAP 2 Sections 8.2.1, 8.2.2, 9.1.2. The info 3 shows prescribing by specialty and 4 compares Actiq prescribers with overall 5 opioid prescribers. 6 So if you could just take a 7 look at this. And there is a colored 8 chart attached to it breaking down 9 primary specialties, Actiq prescriber 10 count, Actiq prescription count, Actiq 11 prescriber percentage, and Actiq 12 prescription percentage. 13 Is this the chart of 14 specialties that your sales and marketing 15 department, or the company, was looking 16 at to ascertain the 15 percent threshold? 17 A. That's what I believe it is. 18 Q. And if you look at the 19 chart, it looks like there is kind of a 20 key in the back of the chart here, on 21 Page -- it must have been an attachment, 22 like a native spreadsheet, so it didn't 23 get a Bates number. But there is a chart 24 on the back with the code to the -- the</p>
<p style="text-align: right;">Page 231</p> <p>1 BY MR. CRAWFORD: 2 Q. All right. And let's mark 3 the next exhibit, then. 4 MR. CRAWFORD: 1693. 5 MR. JENSEN: This is 6 Exhibit-14. 7 - - - 8 (Whereupon, Teva-Marchione 9 Exhibit-14, 10 TEVA_MDL_A_08242504-505, with 11 attachment, was marked for 12 identification.) 13 - - - 14 BY MR. CRAWFORD: 15 Q. It looks like these are 16 the -- take a look at this here. 17 We've marked an e-mail 18 chain. It looks like you're on the one 19 dated May 13th, 2004, from Michael 20 Richardson to Carol Marchione and others, 21 Andy Pyfer; data for 15 percent Actiq 22 prescription meeting. 23 If you go down right to the 24 middle, under, Answers: Attached is the</p>	<p style="text-align: right;">Page 233</p> <p>1 key to the code. 2 But it looks like, if you 3 look at the first page of the chart, AN 4 and APM, they are both pain 5 anesthesiologist categories, right? 6 You may need your magnifying 7 glass for that. 8 A. Yeah, anesthesiology and -- 9 Q. Look, you can look up here 10 on the screen. It might be easier. 11 A. Actually, I can see. 12 APM, it says management, so 13 I'm deducing it's pain management. 14 Q. And AN is anesthesiology. 15 So anesthesiology, total 16 prescriptions is 20 percent, or 19.57 17 percent, that exceeds the 15 percent, 18 right? 19 But it's an excepted 20 category, so you did not do an analysis 21 of whether any of that was off label, 22 right? 23 A. I may not have. I don't 24 know if -- you know --</p>

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<p style="text-align: right;">Page 234</p> <p>1 Q. Right. 2 A. -- I didn't do the analysis. 3 Q. But under the process we 4 just read, that would have been -- that 5 would not have been one of the categories 6 where it's highlighted whether it's above 7 15 percent, right? 8 A. That's my interpretation. 9 Q. And the APM, that's another 10 pain group, that's 12.38 percent. 11 You know, if you combine 12 those, that's 31 percent of the 13 prescriptions are with these pain 14 specialties, right, anesthesiology and -- 15 it looks like some type of pain 16 management, right? 17 A. You know, I'm just hesitant. 18 I don't know what the difference between 19 Actiq prescriber and Actiq TRx means. 20 What's TRx? 21 Q. I think it did come out. I 22 think prescriber is the percentage of 23 prescribers -- of total prescribers, and 24 then the percentage is the percentage of</p>	<p style="text-align: right;">Page 236</p> <p>1 Q. And my question is, as you 2 go to internal medicine, which is IM, a 3 little over halfway down on the next 4 page, that's at 8 percent of 5 prescriptions. 6 So wouldn't internal 7 medicine and family medicine, wouldn't 8 they both be kind of primary care 9 doctors? 10 Shouldn't they be combined 11 as a group, or is that something you left 12 to the marketing department to determine? 13 MR. DIAMANTATOS: Objection 14 to form, foundation. 15 THE WITNESS: That was -- 16 that was evaluated with marketing 17 and legal. 18 BY MR. CRAWFORD: 19 Q. All right. So are these -- 20 would you agree with me that if you've 21 taken out, from looking at the 15 percent 22 threshold for these, quote, targeted 23 groups, and put them aside, and then 24 evaluated all the rest here to see if</p>
<p style="text-align: right;">Page 235</p> <p>1 the prescriptions that are written. 2 So 12 percent of the doctors 3 prescribing the drug are 4 anesthesiologists, and they are 5 prescribing 19.57 of the total 6 prescriptions. 7 Does that -- 8 A. Okay. Yeah -- 9 Q. -- kind of help you 10 interpret that? 11 A. -- that makes sense. 12 MR. DIAMANTATOS: Objection 13 to form. 14 THE WITNESS: I think that 15 makes sense. 16 BY MR. CRAWFORD: 17 Q. So if we look down further, 18 family medicine, it's above 15 percent 19 for the prescriber percentage, but it's 20 at 11 percent for Actiq prescriptions, 21 right? 22 That's the third-to-last 23 one, FM? 24 A. Right. I see that.</p>	<p style="text-align: right;">Page 237</p> <p>1 they rose between the 15 percent 2 threshold, wouldn't you agree with me 3 that these are so cut up that none of 4 them really would realistically rise 5 above 15 percent, so you would never 6 really have a reporting -- you would 7 never really report anything to the FDA, 8 because you would never have a situation 9 where it goes above 15 percent? 10 MR. DIAMANTATOS: Objection. 11 Form. Argumentative. Foundation. 12 THE WITNESS: I mean, I 13 think you can look at it the other 14 way, that it didn't -- I mean, 15 there was no -- there was no 16 algorithm given to us by FDA in 17 how to analyze that. 18 So, you know, I would look 19 at this and say, we did not hit 15 20 percent, based upon the way we 21 interpreted it. 22 And I thought the RiskMAP 23 actually alluded -- 15 percent 24 of -- so I find this as what we</p>

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<p style="text-align: right;">Page 238</p> <p>1 were supposed to do; you know, 2 acceptable within what the 3 parameters of the RiskMAP said. 4 BY MR. CRAWFORD: 5 Q. So the marketing department 6 was -- well, strike that. 7 You would agree, though, 8 that the goal of the RiskMAP was to 9 minimize the amount of off-label 10 marketing, and if there was a problem 11 with off-label marketing, that some type 12 of intervention would take place? 13 Is that really kind of the 14 goal of the RiskMAP, or one of them? 15 MR. DIAMANTATOS: Objection. 16 Form. 17 BY MR. CRAWFORD: 18 Q. In your view? 19 MR. DIAMANTATOS: Same 20 objection. 21 THE WITNESS: What's being 22 prescribed and what's being 23 marketed are two different things. 24 So I think -- yes, I would</p>	<p style="text-align: right;">Page 240</p> <p>1 BY MR. CRAWFORD: 2 Q. And so the RiskMAP also 3 wanted the company to take some type of 4 corrective action, educational action, if 5 it learned that there was an inordinate 6 amount of off-label use, right? 7 MR. DIAMANTATOS: Objection. 8 Form. Vague. Foundation. Calls 9 for speculation. Asked and 10 answered. 11 THE WITNESS: As I said 12 previously, any time that we 13 learned of off-label use from a 14 prescriber, they were informed 15 by -- I believe by a visit and a 16 letter to review the prescribing 17 information. 18 BY MR. CRAWFORD: 19 Q. But also the RiskMAP 20 required, if you learned that groups of 21 prescribers -- you may not have known 22 their names, but if you knew the groups 23 of prescribers were prescribing off label 24 at a certain threshold, that would</p>
<p style="text-align: right;">Page 239</p> <p>1 agree that that's what the RiskMAP 2 is supposed to do. But how people 3 are actually prescribing doesn't 4 necessarily mean that they were 5 marketed to. It means they 6 were -- a fentanyl product and 7 they're trying to address pain. 8 So I feel that you can't 9 necessarily equate the two. 10 BY MR. CRAWFORD: 11 Q. But definitely the FDA was 12 concerned about off-label marketing when 13 it approved it with a RiskMAP, right? 14 That was one of the things 15 that they were -- expressed concern about 16 in the RiskMAP, right? 17 MR. DIAMANTATOS: Objection. 18 Form. Foundation. Calls for 19 speculation. Asked and answered. 20 THE WITNESS: I mean, I 21 would agree with you that the 22 RiskMAP -- you wanted to target 23 marketing to the appropriate 24 people.</p>	<p style="text-align: right;">Page 241</p> <p>1 trigger obligations, on your company's 2 part, to go educate them as a group, 3 not -- you know, not to send them 4 individual letters, but to educate them 5 as a group somehow, even if you don't 6 have direct knowledge of a particular 7 doctor in that group was prescribing off 8 label, right? 9 MR. DIAMANTATOS: Objection. 10 Form. Foundation. Calls for 11 speculation. 12 Go ahead. 13 THE WITNESS: I think the 14 SOP addressed that. That's what 15 it says in the SOP. You just 16 pointed it out to me, from the 17 marketing group, that that's what 18 they would do. 19 Right? I mean -- 20 BY MR. CRAWFORD: 21 Q. Right. 22 But the RiskMAP, the intent 23 was not to just send individual letters 24 when you found out about a doctor who did</p>

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<p style="text-align: right;">Page 242</p> <p>1 it -- that was one aspect, right? 2 But, remember, it's a 3 redundant program, right? 4 MR. DIAMANTATOS: Objection. 5 BY MR. CRAWFORD: 6 Q. They had redundancies within 7 it; you remember reading it, right? 8 MR. DIAMANTATOS: Objection. 9 Form. Foundation. Asked and 10 answered repeatedly. 11 THE WITNESS: The SOP says 12 that. You read it to me. That -- 13 their marketing SOP says that they 14 would do that, right? 15 BY MR. CRAWFORD: 16 Q. No. I'm talking about 17 redundancy. 18 There are redundant 19 mechanisms within the RiskMAP to make 20 sure that the drug is safely used, right? 21 And the redundancy here is 22 not only sending letters to individual 23 prescribers that you learn are 24 prescribing off label, but educating them</p>	<p style="text-align: right;">Page 244</p> <p>1 writing a letter. But it also has the 2 function of education, and that's the 3 RiskMAP. 4 And you're saying that the 5 SOP implements that provision, right, 6 9.1.2 -- 7 A. Right. 8 Q. -- right? 9 A. Yes. 10 MR. DIAMANTATOS: Objection 11 to form. Mischaracterizes 12 testimony. Calls for speculation. 13 Asked and answered. 14 MR. CRAWFORD: Let's go to 15 1143. 16 MR. JENSEN: This will be 17 Exhibit-15. 18 - - - 19 (Whereupon, Teva-Marchione 20 Exhibit-15, 21 TEVA_MDL_A_01405193-5194, was 22 marked for identification.) 23 - - - 24 BY MR. CRAWFORD:</p>
<p style="text-align: right;">Page 243</p> <p>1 on the proper use. 2 But if you learn that groups 3 of prescribers are, that's 9.1.2, there 4 are mechanisms in place to educate that 5 group of prescribers, even if you don't 6 know of particular ones are prescribing 7 off label, right? 8 MR. DIAMANTATOS: Objection. 9 Form. Foundation. Calls for 10 speculation. Asked and answered 11 multiple times. 12 THE WITNESS: If you refer 13 back to the SOP that marketing -- 14 it says that. It says that they 15 will go as a group. The one you 16 just pointed out to me, the 17 marketing one that had approval, 18 that's what it says it will do. 19 BY MR. CRAWFORD: 20 Q. Right. I'm not saying -- 21 I'm not talking about the SOP. I'm 22 just -- I'm talking about the RiskMAP has 23 that function. 24 You were just talking about</p>	<p style="text-align: right;">Page 245</p> <p>1 Q. We marked here an e-mail 2 string. I want to focus in on -- let's 3 start at the second page. 4 It's an e-mail from Tracie 5 Parker to Michael Richardson and others, 6 and you are cc'd on this as well. 7 Subject is, Prescribing specialties - 15 8 percent. It's TEVA_MDL_A_01405193. 9 Ms. Parker is your -- she 10 reports to you, correct, in the 11 regulatory department? 12 A. She did. 13 Q. Yes. All right. 14 So she writes, Michael, in 15 follow-up to the meeting today to review 16 the RMP, attached are the data from the 17 18th and 19th RMP quarterly reports, re 18 the breakdown of the prescribing 19 specialties. You will see that both AM 20 and PM are above 15 percent but are 21 considered to be targeted specialties. 22 Dan, correct me if I'm wrong. To date we 23 have been able to make the statement that 24 none of the nontargeted physician</p>

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<p style="text-align: right;">Page 246</p> <p>1 specialties have exceeded 15 percent. 2 The data is forwarded to me each quarter 3 by Dan Winkelman, Mark Solomon. 4 Dan Winkelman and Mark 5 Solomon, is that -- are they in the 6 marketing department? Who are they? 7 A. I think so. 8 Q. So, basically, it's reported 9 to the FDA -- what she's saying, really, 10 here -- is it your interpretation that 11 she is saying that you only report to the 12 FDA if a nontargeted specialty is 13 identified as exceeding 15 percent?</p> <p>14 MR. DIAMANTATOS: Objection 15 to form. Foundation. Calls for 16 speculation.</p> <p>17 THE WITNESS: That's what I 18 explained before. That was -- 19 that was our interpretation of 20 9.1.2.</p> <p>21 BY MR. CRAWFORD: 22 Q. Okay. And if -- the 23 nontargeted specialties, is the 24 assumption made that those prescriptions</p>	<p style="text-align: right;">Page 248</p> <p>1 MR. DIAMANTATOS: Objection. 2 Asked and answered over and over 3 again. 4 MR. CRAWFORD: I'm just 5 asking in relation to this. 6 MR. DIAMANTATOS: Then make 7 that clear from your question, 8 because you've asked these 9 identical questions repeatedly on 10 the record. 11 THE WITNESS: That was my 12 interpretation. It's all -- it's 13 all kind of the same thing. 14 BY MR. CRAWFORD: 15 Q. All right. So going back to 16 the first page. 17 Mr. Pyfer writes to Michael 18 Richardson, copying you, My opinion would 19 be to change this aspect of the RMP and 20 to track only those specialties that we 21 don't want to see prescribing Actiq 22 because their primary patient populations 23 pose a risk (where Actiq is 24 contraindicated). These would be</p>
<p style="text-align: right;">Page 247</p> <p>1 are off label, if they're in that? 2 A. The nontargeted would be the 3 groups that wouldn't -- wouldn't be 4 usually associated with cancer patients. 5 Q. Right. And so the 6 presumption is that if one of those 7 groups exceed the 15 percent, then you 8 can assume that, potentially, that's over 9 15 percent of the total Actiq 10 prescriptions being prescribed off label, 11 and so that's when the education function 12 starts, correct? 13 MR. DIAMANTATOS: Objection. 14 Form. 15 THE WITNESS: That's my 16 understanding. 17 BY MR. CRAWFORD: 18 Q. Okay. And then, again, 19 anesthesiology and PM are above 15 20 percent, those are the targeted groups, 21 anesthesiology and pain management. 22 But there's no reporting 23 requirement because they're targeted, 24 right?</p>	<p style="text-align: right;">Page 249</p> <p>1 dentists, surgeons, minus oncology 2 surgeons, and pediatric specialties, 3 (until we have a label for this 4 population). Wouldn't this make more 5 sense than trying to determine 6 inappropriate prescribing based on a 7 specialty? 8 And then he writes, How can 9 anyone in this world possibly determine 10 how a pain specialist (whether it is an 11 anesthesiologist, internal medicine, 12 psychiatrist, FP/GP, et cetera) is 13 prescribing Actiq? Focusing on and 14 tracking the specialties that are risky 15 specialties, based on our 16 contraindications, is the best way to 17 minimize the risk of Actiq being used in 18 unintended patient populations, isn't it? 19 Ultimately, isn't the purpose of the RMP 20 to minimize the risk in unintended 21 patient populations, not to try to guess 22 how physicians, especially skilled opioid 23 prescribers, are practicing medicine? 24 So Mr. Pyfer, in effect,</p>

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<p>1 wants to -- wants to reduce even further 2 the examination of the 15 percent 3 threshold by just looking only whether 4 the contraindicated specialties are 5 exceeding 15 percent, and he lists them 6 there, the surgeons and the dentists and 7 the pediatric specialties, right?</p> <p>8 MR. DIAMANTATOS: Objection 9 to form. Calls for speculation.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: That's my 12 interpretation of what he's 13 saying.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. And he's also telling you 16 here that there's no way -- he says, How 17 in the world can you possibly tell, 18 within a specialty, if they're 19 prescribing off label?</p> <p>20 That's what he's explaining, 21 right?</p> <p>22 A. Right.</p> <p>23 MR. DIAMANTATOS: Objection 24 to form. Calls for speculation.</p>	<p>1 reason why you're prescribing -- 2 this is my understanding, whether 3 it's true or not it's my 4 understanding.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. Fair enough.</p> <p>7 A. When you prescribe 8 something, it doesn't say for cancer 9 pain -- it doesn't say what it's for, 10 it's just a prescription.</p> <p>11 So I believe the issue is, 12 how do you know if they're prescribing 13 anything for cancer patients? I mean, 14 even a dentist could prescribe it for 15 cancer patients.</p> <p>16 So this was the dilemma that 17 is on the table, in terms of how -- how 18 do you sift out who is a target, who 19 isn't? I mean, it was a real dilemma.</p> <p>20 And all that I'm reading 21 here is, by introducing this to the 22 FDA -- he's saying try to make the 23 change -- then at least it opens a 24 dialogue, and then you can get the FDA's</p>
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<p>1 BY MR. CRAWFORD:</p> <p>2 Q. Is that -- is that what 3 he -- and that's what he's telling you is 4 that that can't be done, right?</p> <p>5 MR. DIAMANTATOS: Objection 6 to form. Calls for speculation.</p> <p>7 THE WITNESS: That's my 8 understanding.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 A. So is that one reason why, 11 when you took the targeted specialties, 12 that there was no effort made to -- is it 13 your understanding that no effort was 14 made to determine, within those targeted 15 specialties, whether -- what was being 16 prescribed off label.</p> <p>17 MR. DIAMANTATOS: Objection. 18 Form. Asked and answered.</p> <p>19 THE WITNESS: I don't know 20 enough of how -- you know, the 21 data -- I think the key all comes 22 down to is you don't know, when 23 you're prescribing for somebody, 24 if they have cancer. And the</p>	<p>1 interpretation.</p> <p>2 All we had was back in 1998 3 or '99 the FDA's, you know, limited 4 understanding, before the product was 5 even launched. And as time went on and 6 we learned more, what we were always 7 trying to look for was a dialogue with 8 the agency of how we -- what we were 9 doing. I mean, as I said, we kept trying 10 to do that.</p> <p>11 And I feel that we were at 12 least successful in relaying our 13 concerns, our limitations in how to do 14 this, when we went to this July 4th 15 meeting. Because we were very open 16 there, if you look through this whole, 17 huge document that I put together in four 18 days, and read very carefully, is that it 19 was really impossible to really match up, 20 you know, you have cancer with -- with 21 what your prescriber --</p> <p>22 So it was a real dilemma in 23 trying to -- in trying to perform the 24 risk management process as much as that</p>

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<p style="text-align: right;">Page 254</p> <p>1 was initially written. 2 And we tried to do our best. 3 We tried to do an interpretation. But we 4 really wanted a dialogue with the agency 5 to try to get -- so they could understand 6 what we were up against. And that's 7 what, probably, you're seeing in a lot of 8 these back-and-forth. 9 And, again, I think we were 10 successful when we did go to the agency 11 to try to explain what our dilemmas were 12 and how we were doing it. 13 Q. And one dilemma was, Mr. 14 Pyfer's pointing it out, you can't tell, 15 within a certain specialty, what the 16 specialist is prescribing it for, whether 17 it's cancer or noncancer? 18 A. That's exactly -- that's 19 exactly it. 20 Q. And that was your 21 understanding, up until this day, is 22 that's not -- that wasn't possible during 23 this time period, right? 24 A. That's my understanding.</p>	<p style="text-align: right;">Page 256</p> <p>1 working on it multiple times. I think, 2 at this point, you know, I was saying I 3 want management's decision on this, I 4 wanted -- so new people came, new 5 management people came within Cephalon, 6 and I just wanted everyone to understand 7 it. 8 And so that's what this is 9 about, especially because my boss was 10 new. 11 Q. And that's Mr. Raczkowski? 12 A. Raczkowski. Doctor. 13 Q. Dr. Raczkowski? 14 A. I think so, yes. 15 MR. CRAWFORD: Let's pull up 16 Exhibit -- Document 231. 17 MR. JENSEN: This will be 18 Exhibit-16. 19 - - - 20 (Whereupon, Teva-Marchione 21 Exhibit-16, TEVA_CHI_0043010-0983, 22 was marked for identification.) 23 - - - 24 BY MR. CRAWFORD:</p>
<p style="text-align: right;">Page 255</p> <p>1 Like this IMS -- I 2 understood that the IMS database couldn't 3 capture that. I don't know if it can. I 4 can't imagine how. But that's my limited 5 understanding. 6 Q. All right. And then you 7 respond, Andy, I'm in agreement and I'm 8 trying to think of the best way to 9 support this in the revision to the FDA. 10 That's a revision of the 11 RiskMAP, right? 12 A. That's correct. 13 Q. I think that this point will 14 be a discussion point at a meeting that 15 I'm trying to set up, as suggested by 16 Victor, to discuss the more critical 17 issues with the VP level. I think 18 certain stakeholders, such as you, would 19 be invited. Thanks for your input. 20 Carol. 21 So you're, at a point, 22 working on a revision to the RiskMAP to 23 the FDA, right, the Actiq RiskMAP? 24 A. Again, I think we were</p>	<p style="text-align: right;">Page 257</p> <p>1 Q. What I'm giving you here is 2 the 2005 Actiq marketing plan, 3 TEVA_CHI_00043010. 4 This is -- were you involved 5 at all in preparing or reviewing the 6 marketing plans at Cephalon? 7 A. I don't think so. 8 Q. And did you review them at 9 all for whether they were complying with 10 the RiskMAP, or did you depend on sales 11 and marketing, or other departments, to 12 do that? 13 A. This is an internal document 14 to marketing. And I didn't review 15 internal documents. 16 Q. All right. And you see Andy 17 Pyfer is listed as the first name under 18 product director, right? 19 A. Yes. 20 Q. And you agree with me, at 21 least from the front of it, it looks like 22 the 2000 Actiq marketing plan, right? 23 A. That's what it says. 24 Q. And this is -- that stick</p>

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<p style="text-align: center;">Page 258</p> <p>1 there is your understanding of what the 2 Actiq product looks like; that they put 3 in their mouth with the dissolved lozenge 4 at the top, right?</p> <p>5 A. That's correct.</p> <p>6 MR. DIAMANTATOS: Objection. 7 Did you say 2000 Actiq marketing 8 plan?</p> <p>9 MR. CRAWFORD: 2005.</p> <p>10 MR. DIAMANTATOS: I think 11 the record --</p> <p>12 MR. CRAWFORD: Let the 13 record --</p> <p>14 MR. DIAMANTATOS: I heard 15 2000, and I think that's what the 16 record reflects. I just want to 17 be clear we're talking about the 18 same thing.</p> <p>19 MR. CRAWFORD: Thank you. 20 Yes.</p> <p>21 BY MR. CRAWFORD: 22 Q. We're looking at the 2005 23 Actiq marketing plan. 24 So if you could look at Page</p>	<p style="text-align: center;">Page 260</p> <p>1 According to that SOP it 2 didn't fall within one of the targeted 3 specialties, right? 4 A. It wasn't a subcategory. I 5 don't know how -- you know, I don't know 6 how -- when you have groups of umbrellas, 7 I don't know how they're interpreting 8 this.</p> <p>9 Q. But, certainly, it doesn't 10 fall within the SOP list of pain 11 specialists or oncologists? 12 A. It said examples -- it said 13 examples of pain -- again, this is an 14 internal marketing document. 15 So I'm not quite -- you 16 know, I don't think I've seen this 17 before. So I don't know how they're 18 delineating things.</p> <p>19 Q. Sure. Fair enough. Okay. 20 But 20 percent is to primary 21 care providers, PCP. 22 Do you see that? 23 A. I see that. 24 Q. That exceeds 15 percent,</p>
<p style="text-align: center;">Page 259</p> <p>1 22. This plan divides out -- on the top, 2 there are two charts, percent of 3 prescriptions -- TRx is prescriptions, 4 right? 5 A. That's what you explained. 6 Q. Is that your understanding 7 of what TRx is? 8 MR. DIAMANTATOS: Objection. 9 Foundation. 10 THE WITNESS: I wasn't sure. 11 But that's what you told me 12 earlier. 13 BY MR. CRAWFORD: 14 Q. All right. Assuming it's 15 prescriptions, percent of prescriptions 16 by specialty, it lists, basically, five 17 specialties, plus other. 18 First being oncology, this 19 is for June 2003, is 3 percent. And it 20 lists also for 2004, it's 3 percent. 21 Neurology is 7 percent, and it's at 8 22 percent. 23 Now, neurology is a 24 nontargeted specialty, right?</p>	<p style="text-align: center;">Page 261</p> <p>1 right? 2 A. 20 is bigger than 15, yes. 3 Q. And it carries over 21 4 percent in June 2004. 5 June 2004 is about the time 6 that you're communicating with Mr. Pyfer 7 here; his e-mail to you is May of 2004. 8 So this is about the time 9 you guys are talking about this 15 10 percent level, right? 11 MR. DIAMANTATOS: Objection. 12 Form. 13 THE WITNESS: What's the 14 date? Maybe. I'll have to check 15 up -- the dates. 16 What's the date of this? 17 BY MR. CRAWFORD: 18 Q. I don't know if there's a 19 date on the document. 20 A. So then I can't answer that 21 question. 22 Q. But I'm just looking at the 23 chart date. It says, June 2004, the 24 prescriptions reference for that date are</p>

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<p style="text-align: center;">Page 262</p> <p>1 primary care providers at 21 percent, 2 right?</p> <p>3 MR. DIAMANTATOS: Objection. 4 Form.</p> <p>5 THE WITNESS: That's what it 6 says in the document.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. Do you know if Cephalon 9 reported to the FDA that primary care 10 providers had exceeded the 15 percent 11 level, after June of '04, in any of their 12 quarterly reports?</p> <p>13 MR. DIAMANTATOS: Objection. 14 Form. Foundation. Assumes facts.</p> <p>15 THE WITNESS: I don't 16 know -- again, I don't know the 17 interpretation. I don't know PCPs 18 were -- was a target or not. It's 19 hard for me to interpret this, 20 because it's out of context to the 21 RiskMAP, and, really, what they're 22 doing and how they're doing it.</p> <p>23 BY MR. CRAWFORD:</p> <p>24 Q. Well, you depended on the</p>	<p style="text-align: center;">Page 264</p> <p>1 FDA, because you prepared the reports, 2 right?</p> <p>3 MR. DIAMANTATOS: Object to 4 the form.</p> <p>5 THE WITNESS: That's 6 correct.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. You depended on those other 9 departments to let you know what was 10 exceeding 15 percent?</p> <p>11 MR. DIAMANTATOS: Objection. 12 Form. Foundation. Asked and 13 answered.</p> <p>14 THE WITNESS: Yes. After -- 15 initially, we looked at it. And 16 then afterwards we -- it was 17 reviewed by legal and that's how 18 we got it.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. "We" meaning you looked 21 at -- okay, you looked at the report. 22 But legal looked at it. Okay.</p> <p>23 A. When I first was responsible 24 for the RiskMAP quarterlies, I looked at</p>
<p style="text-align: center;">Page 263</p> <p>1 marketing department to tell you when a 2 specialty exceeded 15 percent, right?</p> <p>3 MR. DIAMANTATOS: Objection. 4 Form. Asked and answered.</p> <p>5 THE WITNESS: There was -- 6 the document that you showed me 7 previously, we would get those 8 pages.</p> <p>9 I think, then, when that 10 came out, I believe legal reviewed 11 it, and then -- before it came to 12 me. So if it came to me telling 13 me that it exceeded, that's what I 14 would see.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Right. So you would not 17 make the determination what specialty 18 exceeded 15 percent; you would either be 19 told by marketing or legal, or a 20 combination of the departments?</p> <p>21 A. That's correct.</p> <p>22 Q. So you reported -- if 23 nothing was reported to you exceeding 15 24 percent, it didn't get reported to the</p>	<p style="text-align: center;">Page 265</p> <p>1 the printouts that we saw before. 2 As time evolved, and I can't 3 say exactly when, you know, again, Tracie 4 put these together, so it was up to her 5 to get that information. And I believe 6 that somewhere during that time, legal 7 said that they would double-check, as an 8 interim, before it came to us.</p> <p>9 Q. And one of the other groups 10 is anesthesiology pain, that's in the 11 targeted group, and that was, it looks 12 like, 55 percent of total prescriptions 13 in June 2003, and it went down to 51 14 percent in June of '04.</p> <p>15 Is that what you interpret 16 the charts to reflect there?</p> <p>17 MR. DIAMANTATOS: Objection. 18 Form. Foundation.</p> <p>19 THE WITNESS: I mean, I 20 don't know if they were saying 21 this is -- I mean, if this is what 22 they want to do -- this is a 23 marketing plan. I've never seen 24 this before. I'd have to review</p>

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<p style="text-align: right;">Page 266</p> <p>1 the document.</p> <p>2 I don't know where they were</p> <p>3 going with this. Just seeing</p> <p>4 diagrams, it's hard for me to tell</p> <p>5 you definitively what they're</p> <p>6 trying to do.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. All right. If you could</p> <p>9 look at Page 24 of this marketing plan,</p> <p>10 down at -- actually, Page 24, there's a</p> <p>11 section called, Physician usage.</p> <p>12 Do you see that?</p> <p>13 A. I do see it.</p> <p>14 Q. And then look at the top of</p> <p>15 Page 25, it says, Based on physician</p> <p>16 reporting, 90 percent of Actiq use is for</p> <p>17 BTP -- that's breakthrough pain, right?</p> <p>18 MR. DIAMANTATOS: Objection.</p> <p>19 Form. Foundation.</p> <p>20 THE WITNESS: That's -- yes.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. -- outside of cancer.</p> <p>23 So what this report is</p> <p>24 saying, this marketing report, is that 90</p>	<p style="text-align: right;">Page 268</p> <p>1 what it says in this -- that's</p> <p>2 what it says, if I read it.</p> <p>3 BY MR. CRAWFORD:</p> <p>4 Q. And then it says, The</p> <p>5 majority of use, 55 percent of total, is</p> <p>6 being for chronic back pain.</p> <p>7 That's not a cancer</p> <p>8 indication, right?</p> <p>9 MR. DIAMANTATOS: Objection.</p> <p>10 Form. Foundation. Calls for</p> <p>11 speculation.</p> <p>12 THE WITNESS: I'm a</p> <p>13 regulator. I'm not a clinical</p> <p>14 person. So that's what it says</p> <p>15 here. I agree that that's what it</p> <p>16 says in this document.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. Then there's a chart that</p> <p>19 lists distribution of conditions treated</p> <p>20 with Actiq; the 55 percent back pain is</p> <p>21 referenced and 22 percent headache.</p> <p>22 That's not an indicated</p> <p>23 condition for Actiq, right?</p> <p>24 MR. DIAMANTATOS: Objection.</p>
<p style="text-align: right;">Page 267</p> <p>1 percent of the Actiq use, in their view,</p> <p>2 is off label for noncancer uses, right?</p> <p>3 MR. DIAMANTATOS: Objection.</p> <p>4 Form. Foundation. Calls for</p> <p>5 speculation. She's repeatedly</p> <p>6 said she's not familiar with this</p> <p>7 document.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Is that how you interpret</p> <p>10 the document?</p> <p>11 MR. DIAMANTATOS: Objection.</p> <p>12 Form. Foundation. Calls for</p> <p>13 speculation. Asked and answered.</p> <p>14 THE WITNESS: I mean, I can</p> <p>15 read it just like you. I have the</p> <p>16 same interpretation.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. Does it look like they're</p> <p>19 saying that 90 percent of Actiq use is</p> <p>20 for BTP outside of cancer?</p> <p>21 MR. DIAMANTATOS: Objection.</p> <p>22 Form. Foundation. Asked and</p> <p>23 answered. Calls for speculation.</p> <p>24 THE WITNESS: Again, that's</p>	<p style="text-align: right;">Page 269</p> <p>1 Form. Foundation. Calls for</p> <p>2 speculation.</p> <p>3 THE WITNESS: Actiq is</p> <p>4 indicated for cancer pain.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. Right. But not headache,</p> <p>7 right?</p> <p>8 MR. DIAMANTATOS: Objection.</p> <p>9 Form. Foundation.</p> <p>10 THE WITNESS: You want to go</p> <p>11 through everything?</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. There's just three or four,</p> <p>14 I want to go through them.</p> <p>15 Headache is not an indicated</p> <p>16 use for Actiq, right?</p> <p>17 A. It's not an indicated use</p> <p>18 for Actiq.</p> <p>19 Q. And that's 22 percent,</p> <p>20 according to this chart, right?</p> <p>21 MR. DIAMANTATOS: Objection.</p> <p>22 Form. Foundation. Calls for</p> <p>23 speculation.</p> <p>24 BY MR. CRAWFORD:</p>

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<p>1 Q. And then there's FMS/MPS -- 2 actually, do you know what that means? 3 Fibromyal -- 4 A. Maybe. I don't know. 5 MR. DIAMANTATOS: Objection 6 to form. 7 BY MR. CRAWFORD: 8 Q. Fibromyalgia, myofacial 9 pain? 10 MR. DIAMANTATOS: Objection 11 to form. Calls for speculation. 12 Foundation. 13 BY MR. CRAWFORD: 14 Q. That's not an indicated use 15 in your view as a regulatory specialist 16 in Cephalon, right? 17 A. That's correct. 18 Q. And arthritis is 13 percent, 19 right? 20 A. Total, 13 percent. 21 Q. That's not -- that's not an 22 indicated use for Actiq, right? 23 A. That's not an indicated use. 24 Q. And neuropathy is 12</p>	<p>1 Q. And you agree with me, I'm 2 interpreting malignancy as cancer; is 3 that something that you agree or disagree 4 with? 5 MR. DIAMANTATOS: Objection. 6 Form. Foundation. Asked and 7 answered. Calls for speculation. 8 Argumentative. 9 THE WITNESS: I don't know 10 why it doesn't say cancer pain. 11 So that's why I don't know 12 how they put that as an umbrella. 13 Why wouldn't they have put cancer 14 pain? I don't know. I don't know 15 the answer. 16 BY MR. CRAWFORD: 17 Q. Something normally, in your 18 kind of lay understanding, at least, that 19 malignancy means cancer and 20 nonmalignant -- nonmalignant means not 21 cancer, right? 22 MR. DIAMANTATOS: Objection. 23 Form. Foundation. Calls for 24 speculation. Asked and answered.</p>
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<p>1 percent; again, that's not an indicated 2 use, correct? 3 MR. DIAMANTATOS: Objection. 4 Form. Foundation. Calls for 5 speculation. 6 THE WITNESS: That's not an 7 indicated use. 8 BY MR. CRAWFORD: 9 Q. And then malignant, that -- 10 malignant is cancer, right? 11 MR. DIAMANTATOS: Objection. 12 Form. Foundation. Calls for 13 speculation. 14 THE WITNESS: Yeah, I 15 don't -- I don't know specifically 16 how they got this here. 17 BY MR. CRAWFORD: 18 Q. Right. But malignancy is 19 cancer, right? 20 MR. DIAMANTATOS: Same 21 objections. 22 THE WITNESS: I mean, I'm 23 interpreting just like you are. 24 BY MR. CRAWFORD:</p>	<p>1 Argumentative. 2 THE WITNESS: What do you 3 want me to say? I think I said it 4 all. 5 BY MR. CRAWFORD: 6 Q. It kind of comports with the 7 first sentence, it says, 90 percent of 8 Actiq use is for BTP outside of cancer. 9 So that leaves 10 percent 10 being for cancer, and that chart says 10 11 percent malignancy. So, probably, it 12 links up that the malignancy means cancer 13 in this document, right? 14 MR. DIAMANTATOS: Objection 15 to form. Foundation. Calls for 16 speculation. 17 THE WITNESS: Probably -- I 18 mean, you're saying "probably." 19 That's an interpretation. 20 BY MR. CRAWFORD: 21 Q. And then CRPS, complex 22 regional pain syndrome, is that an 23 indicated use for Actiq in the label? 24 MR. DIAMANTATOS: Objection.</p>

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<p style="text-align: right;">Page 274</p> <p>1 Form.</p> <p>2 THE WITNESS: I have never</p> <p>3 even heard of that before. I</p> <p>4 don't know what complex</p> <p>5 regional -- I never heard that</p> <p>6 syndrome before.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. But it's not cancer, though?</p> <p>9 A. It's a syndrome --</p> <p>10 MR. DIAMANTATOS: Objection</p> <p>11 to form. Foundation.</p> <p>12 THE WITNESS: I don't know</p> <p>13 if it's associated -- I really</p> <p>14 don't know. I'm not being</p> <p>15 facetious. I don't know if the</p> <p>16 syndrome could be associated with</p> <p>17 cancer.</p> <p>18 BY MR. CRAWFORD:</p> <p>19 Q. All right. Well, down below</p> <p>20 that, again, source of the data is an IMS</p> <p>21 patient chart audit, October of 2003.</p> <p>22 Do you see that?</p> <p>23 A. I do.</p> <p>24 Q. Right below.</p>	<p style="text-align: right;">Page 276</p> <p>1 PCP usage is higher for back pain, 81</p> <p>2 percent.</p> <p>3 So primary care physicians,</p> <p>4 PCP, are using it primarily for back</p> <p>5 pain, 81 percent.</p> <p>6 Do you see that?</p> <p>7 A. I see it on the page.</p> <p>8 Q. Now, below that, it says,</p> <p>9 Actiq use by specialty.</p> <p>10 And it lists malignant pain,</p> <p>11 back pain, headache, all the conditions</p> <p>12 that we just went through in that bar</p> <p>13 chart, and it breaks it down by</p> <p>14 specialty.</p> <p>15 So do you see the specialty</p> <p>16 anesthesiology and pain, right there in</p> <p>17 the first column, right?</p> <p>18 MR. DIAMANTATOS: Objection.</p> <p>19 Form. Foundation. Calls for</p> <p>20 speculation.</p> <p>21 Are you just having her</p> <p>22 confirm what's in the document she</p> <p>23 knows nothing about? Is that what</p> <p>24 your questions are calling for?</p>
<p style="text-align: right;">Page 275</p> <p>1 A. I see that.</p> <p>2 Q. So it looks like the source</p> <p>3 of the information was taken from IMS</p> <p>4 data, right?</p> <p>5 MR. DIAMANTATOS: Objection.</p> <p>6 Form. Foundation. Calls for</p> <p>7 speculation.</p> <p>8 THE WITNESS: That's what it</p> <p>9 says in this document.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. And that's October of '03,</p> <p>12 correct? Is that what it says?</p> <p>13 MR. DIAMANTATOS: Objection.</p> <p>14 Form. Foundation.</p> <p>15 THE WITNESS: That's what it</p> <p>16 says.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. And below, it says, It</p> <p>19 should be noted that specialty usage</p> <p>20 tends to fluctuate based on patient</p> <p>21 presentation and physician recognition of</p> <p>22 the need for rapid-acting or BTCP/DTP.</p> <p>23 For example, neurology usage tends to be</p> <p>24 higher for headache, 97 percent, while</p>	<p style="text-align: right;">Page 277</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. Can you answer my question?</p> <p>3 A. It says, Anes -- it says,</p> <p>4 Anes pain in the first column.</p> <p>5 Q. Right. And so it looks like</p> <p>6 this chart, would you agree with me,</p> <p>7 breaks down the usage amongst the</p> <p>8 anesthesiologists and pain specialists,</p> <p>9 right?</p> <p>10 MR. DIAMANTATOS: Objection.</p> <p>11 Form. Foundation. Calls for</p> <p>12 speculation.</p> <p>13 THE WITNESS: I mean,</p> <p>14 respectfully, I'm a regulator.</p> <p>15 This is a marketing plan. So</p> <p>16 there may be somebody else that</p> <p>17 you could talk to that could be</p> <p>18 more -- I'm not trying to be, you</p> <p>19 know, abrasive, but --</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. I know.</p> <p>22 But Mr. Pyfer told you, in</p> <p>23 Exhibit-15, that you couldn't break down</p> <p>24 how the drug was used for what condition</p>

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<p>1 within a specialty. 2 Do you remember that in 3 Exhibit-15? He told you that? He said 4 it was not possible? 5 A. So I -- I don't -- I don't 6 know. I didn't know that. 7 Q. But didn't he tell you that, 8 right? 9 A. Did he? 10 MR. DIAMANTATOS: Objection. 11 Asked and answered. 12 THE WITNESS: I mean, that 13 was my understanding. I guess 14 what I -- the only thing I can say 15 is my understanding, and I don't 16 know about how IMS works, is you 17 can't tell what, specifically, 18 it's being -- I don't know where 19 they got these numbers. I don't 20 know -- I don't know. I mean, 21 that's what I understood. 22 Like, when somebody -- just 23 think about it, when you go get a 24 prescription filled, how do you</p>	<p>1 legal department became involved 2 with them, so I'm also trusting my 3 legal department. 4 And so I don't know. I 5 mean, I just -- there may be a 6 really good response to this, I 7 just don't know the answer. 8 BY MR. CRAWFORD: 9 Q. Right. But I'm just asking, 10 Mr. Pyfer, in Exhibit-15, had informed 11 you that you couldn't tell, within a 12 specialty, how it was prescribed. 13 Do you agree with me that 14 that was what he was conveying to you in 15 Exhibit-15? 16 MR. DIAMANTATOS: Objection. 17 This is getting to the point of 18 badgering the witness. She's 19 answered the same question 20 repeatedly, counsel. And she's 21 doing her best to respond to the 22 question that you've asked 23 multiple times. 24 The problem is that you're</p>
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<p>1 know it's for cancer or not, you 2 know, or a headache? They just 3 write -- they write what it is, 4 not what it's for. 5 So I don't know how they get 6 these numbers. 7 BY MR. CRAWFORD: 8 Q. Right. And Mr. Pyfer told 9 you there's no way to know, right? 10 MR. DIAMANTATOS: Objection. 11 BY MR. CRAWFORD: 12 Q. You're trusting your 13 marketing department telling you that, 14 right? 15 MR. DIAMANTATOS: Objection. 16 Form. Asked and answered. 17 Argumentative. Calls for 18 speculation. 19 BY MR. CRAWFORD: 20 Q. Is that right? 21 MR. DIAMANTATOS: Same 22 objections. Asked and answered 23 multiple times. 24 THE WITNESS: And then my</p>	<p>1 putting documents and asking her 2 things about other people, things 3 outside of her area. 4 This has now gone beyond the 5 point of you badgering the 6 witness, who's answered your 7 question. 8 BY MR. CRAWFORD: 9 Q. Go ahead. You can answer. 10 A. It says, How can anybody in 11 this world possibly determine how a pain 12 specialist is prescribing Actiq? 13 And I don't know. There may 14 be -- I don't know how they get these 15 numbers. I think -- you know, really, if 16 you ask an IMS -- I mean, totally 17 objectively, you get an IMS specialist, 18 they could probably tell you. I don't 19 know how that works. 20 Q. All right. But it does say, 21 Source: IMS patient chart audit, October 22 2003, right below that, right? 23 MR. DIAMANTATOS: Objection. 24 Form. Foundation. Calls for</p>

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<p style="text-align: right;">Page 282</p> <p>1 speculation. Asked and answered. 2 BY MR. CRAWFORD: 3 Q. I'm just saying -- 4 MR. DIAMANTATOS: I'm not 5 done with my objection. 6 Asked and answered 7 repeatedly. 8 MR. CRAWFORD: I don't think 9 I asked that question. That's for 10 sure.</p> <p>11 BY MR. CRAWFORD: 12 Q. Go ahead. 13 A. So it says -- it references 14 IMS. And I highly recommend that you 15 talk to an IMS person to understand how 16 they can analyze. I don't know how that 17 happens.</p> <p>18 Q. Right. You don't know how, 19 right? 20 A. Right. I don't. 21 Q. And so you rely on other 22 people to tell you whether or not it can 23 be done or not. 24 And Mr. Pyfer told you it</p>	<p style="text-align: right;">Page 284</p> <p>1 answered the question as to what 2 Mr. Pyfer told her in the e-mail. 3 She's repeatedly answered that 4 question, counsel. Same 5 objection.</p> <p>6 BY MR. CRAWFORD: 7 Q. So you would agree with me 8 that Mr. Pyfer told you that it couldn't 9 be done, right?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Asked and answered. 12 Go ahead and answer.</p> <p>13 THE WITNESS: I'm reading 14 from his e-mail. If you want me 15 to read what he said, that's all I 16 can do.</p> <p>17 BY MR. CRAWFORD: 18 Q. Sure. 19 A. Is that -- he says, How can 20 you possibly determine how a pain 21 specialist is prescribing Actiq? 22 And he was writing this not 23 to me specifically. He was writing to 24 Michael Richardson, who works for him. I</p>
<p style="text-align: right;">Page 283</p> <p>1 couldn't be done, right? 2 MR. DIAMANTATOS: Objection. 3 Form. Argumentative. Asked and 4 answered.</p> <p>5 THE WITNESS: But -- I think 6 we can do this forever, without 7 having, I think an objective IMS 8 person, you know, take away from 9 fentanyl, from anything, and find 10 out how you can do that. 11 It may be something that 12 Andy is generalizing. I don't 13 know how it was done. I'm really 14 not trying to be --</p> <p>15 BY MR. CRAWFORD: 16 Q. I know you don't know how 17 it's done. I know that. 18 But my question is, he told 19 you it couldn't be done, right? That's 20 all I'm asking. It's yes or no. 21 A. We read it into --</p> <p>22 MR. DIAMANTATOS: Objection 23 as to instructing the witness how 24 to answer the question. She's</p>	<p style="text-align: right;">Page 285</p> <p>1 was copied on it. 2 Q. But you responded to him, 3 correct? 4 And you said, Andy, I'm in 5 agreement. And I'm trying to think of 6 the best way to support this in the 7 revision to the FDA. 8 Right? 9 So you took what he said and 10 were trying to incorporate it into what 11 you were revising to the FDA, right? 12 MR. DIAMANTATOS: Objection. 13 Form. Argumentative. Asked and 14 answered. It mischaracterizes her 15 response to the e-mail, which was 16 not read in its entirety. 17 Go ahead and answer the 18 question.</p> <p>19 THE WITNESS: If I was going 20 to revise -- if I was going to 21 send a revision to the FDA, I'd 22 have to send a white paper 23 supporting why we're saying that, 24 and then I would have all the</p>

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<p>1 documentation, including input 2 from IMS, to understand that. 3 So we -- I don't know if we 4 ever got that far, or where it 5 stood.</p> <p>6 But I would have to 7 understand IMS and how they do the 8 research and how they categorize 9 and -- you know, I don't know 10 whether he's taking this as 11 buckets, or if they are giving him 12 specific analysis. I just -- 13 that's as good as I can do.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. But you depend on the sales 16 and marketing department to give you 17 accurate and honest information, do you, 18 when you're preparing a RiskMAP or a 19 revision to the FDA; is that right?</p> <p>20 MR. DIAMANTATOS: Objection. 21 Form. Asked and answered at least 22 five times.</p> <p>23 THE WITNESS: I depend -- 24 we're all trained in ethics when</p>	<p>1 page. 2 BY MR. CRAWFORD: 3 Q. Okay. 4 A. Okay. 5 Q. Thank you. 6 MR. CRAWFORD: Do you want 7 to take a break? 8 MR. DIAMANTATOS: Why don't 9 we do that. 10 VIDEO TECHNICIAN: Going off 11 the record at 2:22 p.m. 12 - - - 13 (Whereupon, a brief recess 14 was taken.) 15 - - - 16 VIDEO TECHNICIAN: We're 17 back on the record at 2:38 p.m. 18 BY MR. CRAWFORD: 19 Q. Ms. Marchione, I just wanted 20 to ask -- we looked at that marketing 21 plan -- did anyone from marketing ever 22 tell you, in this 2004 time period, that 23 approximately 90 percent of Actiq was 24 being prescribed off label for noncancer</p>
<p>1 we -- where we work. And I depend 2 on everyone, just as, hopefully, 3 they depend on me to be the same 4 way.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. And Mr. Pyfer is the first 7 person listed on this 2005 Actiq 8 marketing plan where, on Page 24, they're 9 breaking out Actiq use by specialty and 10 breaking out the use amongst 11 anesthesiologists and pain specialists, 12 and only 13 percent is used for malignant 13 pain, on label; the rest off label. 14 Would you agree with me 15 there?</p> <p>16 MR. DIAMANTATOS: Objection. 17 Form. Foundation. Calls for 18 speculation. Argumentative.</p> <p>19 THE WITNESS: I can read 20 what you say. I don't know how it 21 got there. I don't know the 22 background behind it. 23 So that's all I can do is 24 agree that that's what is on the</p>	<p>1 pain? 2 MR. DIAMANTATOS: Objection. 3 Form. 4 THE WITNESS: Did anybody 5 tell me? I can't remember. 6 But I did know that there 7 was a considerable amount of off 8 label, not marketing, but sales. 9 BY MR. CRAWFORD: 10 Q. Sales. Okay. 11 And just a couple 12 preliminaries I forgot to take care of. 13 You're represented here by 14 counsel at this deposition, right? 15 A. Yes, I am. 16 Q. And are you being paid at 17 all for your time, by anyone? 18 MR. DIAMANTATOS: Objection. 19 Form. 20 Go ahead. 21 THE WITNESS: No, I'm not 22 being paid today to be -- to be 23 deposed. 24 BY MR. CRAWFORD:</p>

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<p style="text-align: right;">Page 290</p> <p>1 Q. How about for the prep, did 2 you meet with your counsel or any lawyers 3 to prepare for this deposition? 4 A. Yes, I did. 5 Q. And were you paid for that 6 time? 7 A. Yes, I was. 8 Q. And how much were you paid? 9 A. I was paid the rate -- my 10 hourly rate as a consultant. 11 Q. And what's that? 12 A. It's \$275 an hour. 13 Q. And how many hours did you 14 meet before the deposition? 15 A. God. I want to estimate -- 16 it was three days, but they weren't whole 17 days. I don't know, maybe 12 to 15. 18 Q. All right. Thank you. 19 MR. CRAWFORD: We marked the 20 next exhibit. 21 MR. JENSEN: Exhibit-17. 22 - - - 23 (Whereupon, Teva-Marchione 24 Exhibit-17,</p>	<p style="text-align: right;">Page 292</p> <p>1 within the company detailing 2 noncompliance in at least one of these 3 areas. 4 Were you aware that Mr. 5 Brennan had been terminated from 6 Cephalon? 7 MR. DIAMANTATOS: Objection. 8 Form. Foundation. 9 Go ahead. 10 THE WITNESS: I knew he 11 left. I didn't know he was 12 terminated. 13 BY MR. CRAWFORD: 14 Q. You know he left around this 15 time period, after he did the report? 16 A. I didn't -- I didn't connect 17 any correlation. So I didn't -- you 18 know, I just didn't remember. 19 Q. And do you know a gentleman, 20 at all, by the name of Tim Sheehan? 21 A. Yes. I think Tim was his 22 manager. 23 Q. And do you know if he was -- 24 had left the company about this time?</p>
<p style="text-align: right;">Page 291</p> <p>1 TEVA_MDL_A_01159525-527, was 2 marked for identification.) 3 - - - 4 MR. CRAWFORD: It's Document 5 599. 6 BY MR. CRAWFORD: 7 Q. This is document 8 TEVA_MDL_A_01159525. 9 It's a letter from Dave 10 Brennan to Kerry Woods of the FDA, dated 11 February 23rd, 2004. 12 Have you ever seen a copy of 13 this letter before? 14 A. No, I have not. 15 Q. Mr. Brennan writes to Ms. 16 Woods, This letter is to inform you of 17 certain compliance issues at Cephalon, 18 Inc. of 145 Brandywine Parkway, West 19 Chester, PA. As a former employee 20 responsible for conducting quality 21 assurance audits, I'm aware of violations 22 for which the company has taken no 23 action. In fact, I believe my employment 24 was terminated for publishing a report</p>	<p style="text-align: right;">Page 293</p> <p>1 A. You know, I don't remember. 2 Q. Do you know if he was 3 terminated? 4 A. No, I don't. 5 Q. Mr. Brennan continues, As 6 with any company, there are several 7 things that need to be corrected, some 8 more serious and some less. I am aware 9 of several issues, but the most 10 important, and the one for which I 11 believe I was terminated, regards the 12 Actiq (oral fentanyl citrate on a stick) 13 risk management program. 14 This program is a condition 15 of approval in the Actiq NDA, detailing 16 several obligations the company has 17 regarding the monitoring and reporting of 18 marketing, prescribing habits, adverse 19 events, pharmacy compliance and patient 20 education. 21 He continues on, I published 22 an internal audit report, about 1 23 December 2003, detailing the points for 24 which the company was not in compliance.</p>

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<p style="text-align: right;">Page 294</p> <p>1 I do not have a copy of the report 2 available to me at this time. My 3 recollection is the noncompliance in the 4 report includes, among other things, the 5 following points.</p> <p>6 And then you'll see that he 7 does raise the point about the customer 8 surveys of the top four pharmacies and 9 the welcome kit.</p> <p>10 Do you see that in the first 11 point?</p> <p>12 A. I do see that.</p> <p>13 Q. And he does continue -- I 14 want to continue down to the third point.</p> <p>15 He says, The drug is 16 approved for a very narrow therapeutic 17 category. The RMP is designed to assure 18 that the drug is not marketed outside the 19 approved use. The company is required to 20 monitor physician prescribing habits. 21 Physician specialties are described as 22 either representing appropriate patient 23 selection or inappropriate patient 24 selection. If the ratio of prescriptions</p>	<p style="text-align: right;">Page 296</p> <p>1 report. 2 You recall in the report we 3 looked at that you prepared, Section 4 9.1.2 was, in fact, omitted from that 5 report, although you mentioned it had 6 been reported elsewhere, right?</p> <p>7 MR. DIAMANTATOS: Objection. 8 Form. Foundation. Misstates the 9 witness's testimony. Asked and 10 answered.</p> <p>11 THE WITNESS: So if I can 12 just back up. 13 If you saw, like, that table 14 that you showed me where we had to 15 go to the very back page, with the 16 definitions of what the different 17 prescribers were, those are the 18 reports that we used to see in 19 order to make that statement. 20 Unfortunately, Dr. 21 Brennan -- I mean, Mr. Brennan 22 didn't do a very thorough job, 23 that I can tell, when he did this 24 audit. He didn't go to source</p>
<p style="text-align: right;">Page 295</p> <p>1 by specialties representing inappropriate 2 patient selection exceeds 15 percent of 3 the total prescriptions written, the 4 company is required to report this to the 5 FDA and required to conduct physician 6 training programs for the offending 7 specialties.</p> <p>8 And he writes in the first 9 bullet point, In one section of the 10 quarterly reports to FDA, the company 11 simply states that no individual 12 specialty exceeds 15 percent. This 13 statement applies to the three or four 14 specialties designated to represent 15 appropriate patient selection, as well as 16 the dozen or more specialties 17 representing inappropriate patient 18 selection.</p> <p>19 And then he says, In the 20 section corresponding to the specialties 21 representing appropriate versus 22 inappropriate patient selection 23 requirement, nothing is reported. This 24 section is routinely omitted from the</p>	<p style="text-align: right;">Page 297</p> <p>1 documents. And, to me, that's 2 kind of 101 on a QA basis. 3 So if he worked for me, he 4 would have been fired, whether -- 5 I mean, I shouldn't laugh about 6 this, but you go to source 7 documentation in order to find out 8 what was correct and what isn't. 9 I mean, my interpretation of 10 what he did was just look at the 11 report versus what was supposed to 12 be reported, and not really go 13 into the detail. 14 So he didn't really get into 15 the detail of what was available, 16 what was being reported, how 17 things were interpreted. 18 So what -- I'm looking at 19 this, it's not very thorough in 20 terms of his interpretation of 21 what we had available, what was 22 said, what wasn't. 23 He never looked at that 24 table that, you know, we were</p>

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<p style="text-align: right;">Page 298</p> <p>1 talking about, showing where the 2 percentages were. 3 BY MR. CRAWFORD: 4 Q. Can you grab the table that 5 you're referring to? I just want to make 6 sure I know what exhibit that is. 7 Was it 14 you were looking 8 at? 9 A. It was the one that had all 10 the numbers, and then the last page had 11 the definitions. Do you remember that 12 one? 13 Q. Yeah, Page 14 -- or 14 Exhibit-14. 15 A. Exhibit-14. Yes. 16 This is -- so that -- this 17 is the kind of report -- this is from 18 2004. But when I was working on these 19 originally, we would get these and they 20 were always -- and you pointed out, that 21 they were all below 15 percent. 22 And that's what we -- what 23 we would normally use to make that 24 statement.</p>	<p style="text-align: right;">Page 300</p> <p>1 MR. DIAMANTATOS: Objection. 2 Form. Calls for speculation. 3 Go ahead. 4 BY MR. CRAWFORD: 5 Q. What do you think he should 6 have looked at that he didn't look at? 7 A. The -- and this was 2004 -- 8 MR. DIAMANTATOS: Objection 9 to form. 10 Go ahead. 11 THE WITNESS: These tables. 12 BY MR. CRAWFORD: 13 Q. And what would he have found 14 there that might have changed his view of 15 compliance with that provision? 16 MR. DIAMANTATOS: Objection. 17 Calls for speculation. Form. 18 THE WITNESS: The 19 targeted -- he would have sat down 20 and figured out how they 21 identified target versus 22 nontarget, where the numbers would 23 come to. 24 BY MR. CRAWFORD:</p>
<p style="text-align: right;">Page 299</p> <p>1 Q. But how do you know he 2 didn't look at these reports? 3 He mentions 85 specialties 4 that the company used, right? 5 A. Because -- 6 MR. DIAMANTATOS: Object to 7 form. Foundation. Calls for 8 speculation. Argumentative. 9 THE WITNESS: Because I 10 looked in his memo. I don't think 11 he referenced that. 12 He referenced everything he 13 looked at, and I don't see 14 anything about IMS data. 15 Documents and records. He 16 didn't even -- yes, there's 17 nothing in here about looking at 18 IMS data. He didn't go to source 19 documents. 20 BY MR. CRAWFORD: 21 Q. So what would he have found 22 that may have changed his mind about how 23 Cephalon applied the 15 percent? 24 A. He would --</p>	<p style="text-align: right;">Page 301</p> <p>1 Q. But he does say, in Number 2 13 of his report, I think you just had 3 that. 4 He says, There are 5 approximately 85 specialties reported, 6 three of which are included in the list 7 of exemptions in the SOP. 8 So he is obviously aware of 9 the report of all the specialties, right? 10 MR. DIAMANTATOS: Objection. 11 Form. Foundation. Calls for 12 speculation. 13 THE WITNESS: To that point, 14 there's no way -- how would I know 15 that? I can't tell what -- I 16 can't tell what he looked at. I 17 don't know where the 85 came from. 18 BY MR. CRAWFORD: 19 Q. All right. But, obviously, 20 he -- you're criticizing his methodology 21 here, right? 22 A. So I was responsible for 23 compliance, and you always go to source 24 documents. So because I can't understand</p>

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<p>1 which source documents he went to, it 2 wasn't pointed out, that's kind of 3 like -- that's what you learn, when you 4 go into compliance, that your source 5 documents are supposed to agree with your 6 summaries.</p> <p>7 So I'm missing something 8 here. And that's what -- that's what I'm 9 questioning.</p> <p>10 And, I mean, I, maybe, could 11 go through everything that he talked 12 about, and I haven't had time to do that. 13 But I think -- I think a lot of the 14 concerns here is he really didn't delve 15 into the details and ask the right people 16 the right questions.</p> <p>17 Because if you have a 18 concern when you're auditing, you go to 19 the next level. I don't believe Mr. 20 Brennan did that, from looking just at 21 his audit report.</p> <p>22 Q. Well, I mean, he did go -- 23 send this report to Tim Sheehan, which 24 was his boss, you, Bob Bader, Mark</p>	<p>1 and the reason why. 2 I didn't think that this 3 report is that thorough and really 4 supports his findings. And so if I 5 was -- if I had an auditor, and, maybe a 6 beginning auditor, I would mentor them 7 and help them out.</p> <p>8 But if this was somebody -- 9 especially an internal company audit, 10 where you have a lot more flexibility to 11 go down the hall and talk to somebody, I 12 think -- I think that this audit report 13 is not very -- I'll get off my -- you 14 know, I teach this stuff. So I just feel 15 that this isn't a very thorough report.</p> <p>16 Q. Do you know what he did 17 afterwards with regard to this report in 18 discussing it with company officials?</p> <p>19 MR. DIAMANTATOS: Objection. 20 Form. Calls for speculation. 21 Foundation.</p> <p>22 THE WITNESS: No, I don't. 23 BY MR. CRAWFORD: 24 Q. So how can you judge that he</p>
Page 303	Page 305
<p>1 Solomon. 2 So he did give the report 3 and give some ability to respond, right? 4 That was the plan on the 5 bottom here, it says, RA will issue a 6 response audit report by 12/31. 7 That's you, right? 8 A. I wouldn't say this is a 9 thorough initial audit report. 10 So when I would do audits -- 11 or I should say oversee audits -- you 12 know, I used to do GCP. So go to a 13 hospital, you interview some people and 14 you look at documents. But if something 15 unusual occurs, you don't just stop 16 there. Then you go -- you keep trying 17 to, like, figure it out. 18 Because if my auditor came 19 back and gave me a report that I didn't 20 feel like they delved into what the 21 rationale -- it could be a very innocent 22 comment, and they could blow up something 23 that makes it look worse than it is. I 24 expect them to delve into the rationale</p>	<p>1 didn't -- he wasn't thorough on following 2 up on what he found in the report? 3 MR. DIAMANTATOS: Objection. 4 Form. Argumentative. 5 THE WITNESS: Because I -- 6 as an example -- I mean, I didn't 7 go through this thoroughly -- but 8 he should have referenced the IMS 9 data. And you said, okay, well, 10 85. But I don't see any -- I 11 don't know where he's getting that 12 from. It's not clear. 13 Something -- this is 14 important, internal to the 15 company, you should really -- it 16 should be a roadmap to what the 17 findings are. 18 So I don't think this is 19 clear. And I don't want to -- you 20 know, I don't want to throw him 21 under the bus. I didn't have a 22 long time to look at this. But 23 you really have to lay it out. 24 And that's what I would expect</p>

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<p style="text-align: right;">Page 306</p> <p>1 from an auditor of mine. 2 BY MR. CRAWFORD: 3 Q. But Exhibit-14, this is the 4 document -- the type of document you 5 think he should have looked at, right? 6 MR. DIAMANTATOS: Objection. 7 Form. Foundation. Calls for 8 speculation. 9 BY MR. CRAWFORD: 10 Q. That's what you're saying, 11 he should have looked at the IMS -- this 12 data right here, right? 13 A. Not just that, but for 14 everything. 15 Like, so, for instance, you 16 go through each -- and this is what I 17 would expect from an auditor. I would go 18 through each, like, the Walgreens, and 19 then I would go and interpret, okay, 20 well, it's only Walgreens -- what does he 21 say -- Walgreens is the only chain 22 represented. 23 Well, I would have gone to 24 marketing and said, why is it -- you</p>	<p style="text-align: right;">Page 308</p> <p>1 criticisms with Mr. Brennan at the time 2 that he provided you with his audit 3 report? 4 A. He didn't work for me. And 5 I can't remember -- you know, we talked 6 about all these things, and we went 7 through the pieces and why -- and I think 8 my memo addressed some of the issues. 9 Q. So look at Exhibit-12. 10 Did you raise any of these 11 points with him in Exhibit-12, that he 12 failed to do these things? 13 A. So this went to the highest 14 levels of the company, and -- 15 Q. Including Mr. Brennan, 16 right? 17 A. Let me go through here. 18 Well, I mean, for instance, 19 I mean, it wasn't -- you know, trying not 20 to be personal. So, for instance, Number 21 3, the NDC Source Prescriber is used in 22 place of IMS Xponent. 23 Well, I think, if he did a 24 little more research, he would have found</p>
<p style="text-align: right;">Page 307</p> <p>1 know, I would have said, I investigated 2 this and the others can't be represented, 3 because there was -- you know, there was 4 a practical reason why you can't. I 5 don't think they were doing it anymore. 6 I don't remember the details. 7 What I'm saying is you don't 8 just -- you don't just identify issues. 9 At this level, you try to -- you try to 10 find out why, what you did. You don't 11 just scratch the surface, in other words. 12 This is all -- there's a -- 13 you know, if I went through this, there's 14 a lot of benign issues here that if he 15 just did a little more research, he'd 16 find out, for instance, that -- I don't 17 know, I'm making this up, that Eckerd no 18 longer does this, for instance. 19 And I can't remember all the 20 details. But there's a lot of very 21 benign, rational reasons why things 22 weren't done. And I don't think he went 23 that far. 24 Q. Did you raise these</p>	<p style="text-align: right;">Page 309</p> <p>1 out why we were doing that, that they 2 were the same. 3 I'm not going to -- I hope 4 you don't mind. I don't want to get into 5 detail here. But that's just an example. 6 So I'm not going to -- I don't want to -- 7 I'm not going to say, Mr. Brennan should 8 have done a more thorough -- I'm not 9 going to put it that way. But that's 10 kind of inferred. 11 Q. Right. But you agree that 12 it's inconsistent with the RiskMAP, on 13 the Walgreens example, that they're only 14 using Walgreens and not the other four, 15 right? It's just inconsistent with the 16 RiskMAP -- 17 MR. DIAMANTATOS: Objection. 18 BY MR. CRAWFORD: 19 Q. -- right? 20 MR. DIAMANTATOS: Objection. 21 Form. Foundation. Speculation. 22 Asked and answered. 23 THE WITNESS: Right. And as 24 I said previously, there are</p>

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<p style="text-align: right;">Page 310</p> <p>1 inconsistencies. And I told you 2 that, you know, when we started at 3 10:00 or whatever, that a lot of 4 it had to do -- because I said -- 5 I said that operationally things 6 evolved; however, that the -- you 7 know, the function of what we were 8 trying to do stayed the same. 9 So we weren't able to get 10 Eckerd as a contractor, but we 11 were able to get Walgreens, or 12 something. But the intention was 13 we were still doing what the FDA 14 wanted, but we didn't have the 15 ability to communicate a -- I 16 should not say communicate a 17 revision, but to revise it 18 formally; they didn't approve it. 19 But we did communicate to them 20 those issues that we couldn't do 21 this or we couldn't do that. 22 So why Mr. Brennan didn't 23 do -- you know, if he -- if he -- 24 that's just one example. But if</p>	<p style="text-align: right;">Page 312</p> <p>1 Go ahead. 2 BY MR. CRAWFORD: 3 Q. And then it says that -- on 4 his report, on Exhibit-10, he says, Items 5 requiring follow up. The four listed 6 pharmacy chains are not included, as 7 required by Section 8.1.1. Section 8 8 further commits that if any of the four 9 organizations are unable to participate, 10 Cephalon will substitute another 11 supplier. Only Walgreens is represented. 12 So he is not saying this is 13 the final conclusion, but requires follow 14 up, right? 15 MR. DIAMANTATOS: Objection. 16 Form. Calls for speculation. 17 Asked and answered. 18 BY MR. CRAWFORD: 19 Q. So he is opening up the 20 possibility that there needs to be some 21 kind of follow-up on this, right? 22 MR. DIAMANTATOS: Objection 23 to form. Calls for speculation. 24 Foundation. Asked and answered.</p>
<p style="text-align: right;">Page 311</p> <p>1 he had dug a little further, we 2 would say, yes, this is different, 3 and this is the reason why, and we 4 tried to communicate it to the 5 FDA, we did communicate it to the 6 FDA, but it's not yet approved. 7 Something like that. 8 So that's why I'm saying -- 9 I'm not saying there aren't 10 differences. As I said from the 11 very beginning, you'll find 12 inconsistencies. But it wasn't 13 because -- because we kept trying 14 to communicate to the FDA and get 15 it approved.</p> <p>16 BY MR. CRAWFORD: 17 Q. So he should have dug deeper 18 and found out that there was an excuse 19 that you had -- 20 A. That would be my 21 interpretation.</p> <p>22 MR. DIAMANTATOS: Objection. 23 Objection. Mischaracterizes the 24 witness's testimony. Form.</p>	<p style="text-align: right;">Page 313</p> <p>1 THE WITNESS: I didn't read 2 this whole document, but what he 3 sent to the FDA doesn't look 4 like -- I don't get the sense that 5 he said, I did a really thorough 6 investigation and, you know, these 7 people are not doing what they're 8 supposed to. 9 I think that there's holes 10 that he's pointing out that -- or 11 differences, but not explaining 12 why. And it's creating more of an 13 issue than was, in reality -- why 14 the changes were there. 15 BY MR. CRAWFORD: 16 Q. But you said you didn't -- 17 you didn't know what happened with him, 18 with conversations afterwards, right? 19 A. No, I didn't. 20 Q. So possibly he did follow it 21 up, right? But you don't know? 22 MR. DIAMANTATOS: Objection. 23 Calls for speculation. Asked and 24 answered.</p>

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<p style="text-align: right;">Page 314</p> <p>1 BY MR. CRAWFORD: 2 Q. And then he was terminated, 3 so he can't really do anything after he's 4 terminated, right? 5 MR. DIAMANTATOS: Objection. 6 Assumes facts. Asked and 7 answered. The witness said she 8 doesn't know how he left the 9 company.</p> <p>10 BY MR. CRAWFORD: 11 Q. He says he was terminated, 12 right? 13 A. Yeah, I really -- I 14 really -- I don't know. I really don't 15 know.</p> <p>16 Q. But you saw that he said in 17 his letter to the FDA that he was 18 terminated, right?</p> <p>19 A. Here, yes.</p> <p>20 MR. DIAMANTATOS: Objection. 21 Form.</p> <p>22 BY MR. CRAWFORD: 23 Q. All right. So Mr. Brennan's 24 letter, Exhibit-17, is dated February</p>	<p style="text-align: right;">Page 316</p> <p>1 mark the next document, 1692. 2 - - - 3 (Whereupon, Teva-Marchione 4 Exhibit-18, 5 TEVA_MDL_A_08242371-373, was 6 marked for identification.) 7 - - - 8 MR. JENSEN: This is 9 Exhibit-18.</p> <p>10 BY MR. CRAWFORD: 11 Q. So this is an e-mail you 12 wrote to Francine Del Ricci in June of -- 13 June 7th, 2004, re: FDA contact report. 14 FDA raises concerns about Actiq off-label 15 use and diversion working document.doc -- 16 and diversion. 17 There's an attachment, 18 working document.doc? 19 A. So I actually forwarded it 20 to her. I didn't write it to her. Just 21 to be clear. 22 Q. Sure. 23 You wrote down below -- 24 that's right. Your e-mail below is dated</p>
<p style="text-align: right;">Page 315</p> <p>1 23rd, 2004, correct? 2 A. The FDA -- give me one 3 second. 4 Q. Exhibit-17. 5 A. Give me one second here.</p> <p>6 MR. DIAMANTATOS: Objection. 7 Foundation.</p> <p>8 THE WITNESS: Here we go. 9 I'm gong to move -- give me one 10 second. I'm going to move 11 everything back --</p> <p>12 BY MR. CRAWFORD: 13 Q. Take your time. 14 A. -- to the pile. Okay. 15 I've got it in front of me.</p> <p>16 Q. Just, the date is February 17 of 2004, right?</p> <p>18 MR. DIAMANTATOS: Objection. 19 Foundation.</p> <p>20 THE WITNESS: February 23rd.</p> <p>21 BY MR. CRAWFORD: 22 Q. Yes. 23 A. Yes.</p> <p>24 MR. CRAWFORD: I want to</p>	<p style="text-align: right;">Page 317</p> <p>1 June 4th, 2004, to a number of people, 2 including high up in the company. You 3 had mentioned Paul Blake, Ed Berg and 4 others. 5 The subject is, FDA contact 6 report, FDA raises concerns about Actiq 7 off-label use and diversion. 8 Is that an e-mail that you 9 wrote? 10 A. Yes, it is. 11 Q. And you write, Attached is a 12 telephone contact report detailing the 13 phone call that I received yesterday from 14 Bob Rappaport, director of the division 15 of anesthetic, critical care and 16 addiction drug products. He expressed to 17 me that high levels of FDA are very 18 concerned about information that they 19 have analyzed that reflect staggering 20 off-label use and increasing reports of 21 diversion, misuse and unintended 22 pediatric use of Actiq. He is requesting 23 that a Cephalon representative come to 24 FDA within the next couple of months to</p>

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<p>1 discuss. He asked for a meeting package 2 prior to this.</p> <p>3 And this is what you 4 reported.</p> <p>5 Did you take that call from 6 the FDA personally?</p> <p>7 A. Yes, I did.</p> <p>8 Q. And did he, in fact, report 9 a staggering off-label use that he was 10 aware of?</p> <p>11 MR. DIAMANTATOS: Objection. 12 Form.</p> <p>13 THE WITNESS: I believe I 14 tried to capture his words, so --</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. And you agree, at this time 17 you knew that the off-label use was high, 18 you testified, right?</p> <p>19 A. Yes.</p> <p>20 Q. Did you know it was 90 21 percent, or thereabouts?</p> <p>22 A. I didn't -- I didn't know 23 the actual amount.</p> <p>24 Q. So he asked for a meeting</p>	<p>1 company. One of the intentions of the 2 risk management program was to limit the 3 use of the product to the indication, and 4 the reports that they are receiving 5 regarding off-label use have them 6 extremely concerned. Their sources 7 reflect that many of the elements that 8 the RiskMAP was intended to control, such 9 as off-label use, especially, but also 10 pediatric exposure, diversion and abuse, 11 are increasing. These analyses are 12 causing a real concern at high levels of 13 the agency -- in the agency.</p> <p>14 And, again, at the very end 15 of the paragraph, the report states, He 16 reiterated that the off-label use of the 17 product is staggering.</p> <p>18 So you agree here, I mean, 19 just from the tenor of the call that you 20 took from him, that they were very 21 concerned at the FDA about the off-label 22 use, right?</p> <p>23 MR. DIAMANTATOS: Objection. 24 Calls for speculation. Form.</p>
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<p>1 package prior to this. 2 Was that package sent to 3 him?</p> <p>4 A. Yes, it was.</p> <p>5 Q. And was that the Exhibit-11 6 that you sent?</p> <p>7 A. Yes.</p> <p>8 Q. Let's go to the actual 9 report you attach here. It's a 10 regulatory telephone contact report from 11 you.</p> <p>12 And the discussion says 13 that, Dr. Rappaport stated that the FDA 14 is very concerned about reports of 15 diversion and misuse of Actiq.</p> <p>16 That's the first sentence.</p> <p>17 Going to the second 18 paragraph, it states, Dr. Rappaport 19 stated that the agency's concern stems 20 from analysis and reports that have come 21 to the FDA's attention from review of 22 their sources. He stated that rather 23 than discussing specific details, the 24 agency would like to meet with our</p>	<p>1 Go ahead.</p> <p>2 THE WITNESS: And what 3 triggered the call, which was 4 stated here, was one case of 5 diversion that made the -- that 6 made the news. And that's what 7 triggered the call. And the rest 8 of the concerns he had there.</p> <p>9 But it was -- it was that 10 the -- what do you call it -- the 11 API, whatever is on the wire, that 12 there was a Philadelphia case, 13 specifically, of diversion of 14 Actiq is what triggered that call.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. So was it -- doesn't he say 17 here that the concern for the staggering 18 amount of off-label use is also a trigger 19 of the call?</p> <p>20 A. What was relayed to me, and 21 what I put into -- let me see -- it says, 22 In addition, please refer to conversation 23 requesting the source of Actiq use of the 24 Philadelphia diversion case.</p>

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<p style="text-align: right;">Page 322</p> <p>1 So that may have been a call 2 even before this one. There may have 3 been two calls. But that's what started 4 it.</p> <p>5 And then -- I think then 6 he -- then he discussed the off-label use 7 also. I'm not negating it, I'm just 8 saying that's what first triggered it.</p> <p>9 Q. But one of the purposes of 10 this particular call was the staggering 11 off-label use that had come to the 12 attention of the FDA and caused great 13 concerns high up in the FDA, right?</p> <p>14 MR. DIAMANTATOS: Objection. 15 Form. Calls for speculation. 16 Assumes facts.</p> <p>17 BY MR. CRAWFORD: 18 Q. Is that what he told you? 19 A. Well, if you read the first 20 sentence, it says -- he talks about the 21 diversion of the product that -- a single 22 incident of diversion that occurred in 23 the beginning of the year in the 24 Philadelphia area.</p>	<p style="text-align: right;">Page 324</p> <p>1 the attention of the company regarding 2 the diversion of the product that 3 virtually stem from a single instance 4 of -- incident of diversion that occurred 5 in the beginning of the year in the 6 Philadelphia area.</p> <p>7 So you're -- so that's what 8 you told him, right, about the 9 Philadelphia incident? He did not 10 tell --</p> <p>11 A. No, he --</p> <p>12 Q. -- you about it; you told 13 him.</p> <p>14 A. Maybe this was -- no, that's 15 what he first called me about. That's 16 what triggered this.</p> <p>17 And then we talked -- again, 18 I'm not denying that he said everything 19 else. But that's what was the trigger, 20 because it made the news and he was 21 getting pressure from his management.</p> <p>22 Q. Well, it seems like -- it 23 seems like he was a little more concerned 24 about the one -- a little bit more</p>
<p style="text-align: right;">Page 323</p> <p>1 Q. That's what you explained to 2 him, right --</p> <p>3 A. No, no.</p> <p>4 Q. -- not what he said to you?</p> <p>5 A. No, no, that's what he 6 initially called for.</p> <p>7 I remember this very 8 clearly. Because I heard about it and 9 contacted DEA first, and I was getting 10 ready to pick up the phone to FDA. And 11 he called me before I had a chance to 12 call him.</p> <p>13 So that's how the call 14 started. And then he said the rest of 15 the information.</p> <p>16 Q. Didn't the call start with 17 him saying the FDA is very concerned 18 about reports of diversion and misuse of 19 Actiq? He said that there had been 20 discussions at very high levels of the 21 agency regarding several issues involving 22 the use of our product.</p> <p>23 You state, I explained that 24 recent published articles have come to</p>	<p style="text-align: right;">Page 325</p> <p>1 concerned than just about the one 2 incident of diversion in Philadelphia, 3 right?</p> <p>4 MR. DIAMANTATOS: Objection. 5 Form. Foundation. Calls for 6 speculation. Asked and answered. 7 Argumentative.</p> <p>8 THE WITNESS: As you -- as 9 you can read here, the answer is 10 yes, because I wrote this.</p> <p>11 But I'm just saying how 12 the -- the course of the 13 conversation started with the 14 Philadelphia incident.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. And then at the bottom of 17 the page, that last paragraph, you say, 18 He stated that he was very much involved 19 with the drafting of our RiskMAP, RMP, 20 that he knows this document very well and 21 the agency is very concerned that the 22 situation that occurred with OxyContin 23 may happen again. He further stated that 24 the RMP was designed to limit the use of</p>

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<p>1 the product to the indicated use and this 2 does not seem to be working. 3 So he is telling you that 4 the RiskMAP is not working, correct? 5 A. That's what he communicated 6 in this -- as I captured it. 7 Q. So he -- it continues, Dr. 8 Rappaport stated that he would like our 9 company to come in for a meeting in a 10 month or two to provide a review of the 11 data on misuse, diversion, off-label use, 12 deaths, pediatric exposure, addiction and 13 abuse. 14 So that was the intent of 15 the meeting that he wanted to call, 16 right? 17 A. That's correct. 18 Q. And did that meeting, in 19 fact, occur? 20 A. Yes, it did. 21 Q. And was that the mid July 22 meeting of 2004? 23 A. Yes, it is. 24 Q. All right. You stated that,</p>	<p>1 question. 2 THE WITNESS: Okay. 3 MR. DIAMANTATOS: I'm going 4 to object to you interrupting her 5 answering your question. 6 BY MR. CRAWFORD: 7 Q. All right. I'll withdraw 8 the question. 9 MR. CRAWFORD: Let's mark 10 the next exhibit, Doc 1689. That 11 will be Exhibit-19. 12 - - - 13 (Whereupon, Teva-Marchione 14 Exhibit-19, 15 TEVA_MDL_A_03317918-921, was 16 marked for identification.) 17 - - - 18 BY MR. CRAWFORD: 19 Q. This is an FDA letter. On 20 the back page, they have the date, June 21 29th, 2004, from the FDA, including Mr. 22 Rappaport, to Anesta Corporation, care of 23 Cephalon, attention to your attention. 24 Do you recall receiving this</p>
<p>1 I concluded that our company is also 2 concerned about the proper use of our 3 product. 4 But we saw in that marketing 5 plan that there was a reference to 90 6 percent off-label usage. 7 Did you see any concern in 8 that marketing document about the 9 off-label usage, or was it looked upon as 10 a business opportunity by the company? 11 MR. DIAMANTATOS: Objection. 12 Form. Entirely argumentative. 13 Improper question. Foundation. 14 Calls for speculation. 15 THE WITNESS: We actually 16 relayed all this information to 17 the FDA. 18 So I wanted to go in here to 19 see what we talked about off 20 label, so I can -- I think that's 21 a nice way of -- 22 MR. CRAWFORD: Your counsel 23 can ask questions on that. I'm 24 going to move to the next</p>	<p>1 letter from the FDA? 2 A. Not specifically. But I 3 remember this meeting that went with it. 4 Q. Okay. So they're writing to 5 you saying, We also refer to your 6 telephone conversation with Dr. Rappaport 7 on June 3, 2004 -- that was Exhibit-18 8 that we just looked at, right? 9 A. That's correct. 10 Q. -- in which he requested 11 that Cephalon meet with the agency to 12 present all of the available information 13 on certain aspects of the Actiq product. 14 And he writes -- or the FDA 15 writes, We are particularly concerned 16 that Actiq be promoted strictly within 17 its approved indication and only to 18 the -- its appropriate target audience. 19 We remind you that, per the indications 20 and usage section of the Actiq package 21 insert, Actiq is intended to be used only 22 in the care of cancer patients and only 23 by oncologists and pain specialists who 24 are knowledgeable of and skilled in the</p>

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<p style="text-align: right;">Page 330</p> <p>1 use of Schedule II opioids to treat 2 cancer pain. 3 As you know, these 4 restrictions are an important part of the 5 risk management program for the drug, to 6 discourage inappropriate and potentially 7 dangerous misuse of the drug. We would 8 like representatives promoting Actiq -- 9 or for receiving -- I'm sorry.</p> <p>10 We would like to know how 11 your company targets physicians that are 12 not oncologists for visits by sales 13 representatives promoting Actiq. 14 So in this letter, he's 15 requesting the type of information that 16 he'd like to receive for the meeting, 17 correct?</p> <p>18 A. Right.</p> <p>19 MR. DIAMANTATOS: Objection 20 to form. Calls for speculation. 21 Foundation.</p> <p>22 BY MR. CRAWFORD:</p> <p>23 Q. And he says, We would like 24 to know the steps your company takes to</p>	<p style="text-align: right;">Page 332</p> <p>1 A. I am. I'm trying to see if 2 there was a table of contents. 3 I mean, the RiskMAP is in 4 there, a lot of IMS data, sales. 5 Everything they asked for is included, 6 including all the marketing information. 7 The Dave Brennan audit report is in 8 there. All of our safety information. 9 There's tables on off-label use, misuse and abuse.</p> <p>10 I don't see a table of 11 contents. Oh, here it is. 12 Do you want me to go through 13 each attachment and say where it came 14 from? Is that -- I mean, I'm not quite 15 sure what you'd like.</p> <p>16 Q. I just wanted to know, 17 generally, where did you get information 18 to answer the question. I don't need to 19 know specific. If you don't know 20 generally, that's fine, we can skip 21 ahead.</p> <p>22 A. Generally, the safety group, 23 the commercial group. We got the audit</p>
<p style="text-align: right;">Page 331</p> <p>1 ensure that there is no confusion about 2 the appropriate indicated use of this 3 drug. We are aware that your company 4 disseminates unbranded disease awareness 5 materials discussing breakthrough pain 6 generally. Please inform us whether 7 these materials are ever used in 8 conjunction with promotion of Actiq, 9 e.g., as part of a detail in which the 10 sales rep also discussed Actiq, or 11 disseminated with printed materials for 12 Actiq.</p> <p>13 Now, these requests for 14 information from the FDA for the meeting, 15 who, at your company, was in charge of 16 putting this together to present to the 17 FDA for the meeting?</p> <p>18 A. I was.</p> <p>19 Q. And where did you collect up 20 this particular information that he's 21 requesting?</p> <p>22 A. From all over the company.</p> <p>23 Q. And you're looking at 24 Exhibit-11, correct?</p>	<p style="text-align: right;">Page 333</p> <p>1 report from QA. We got all the promotion 2 from marketing. Legal gave us some 3 initiatives.</p> <p>4 Q. So this letter, the July 5 12th letter that you wrote here, is 6 this -- you wrote this letter, correct?</p> <p>7 A. I'm sure there was a huge 8 input from many people.</p> <p>9 Q. All right. So there were 10 drafts that went around, but you kind of 11 spearheaded the effort to put it 12 together, right?</p> <p>13 A. Yes, that's correct.</p> <p>14 Q. And if you could look at 15 Page 8, the last paragraph, it states, 16 Prescriber data obtained by Cephalon from 17 IMS, NDC and Verispan do not provide any 18 conclusive information as to the 19 diagnosis of each patient at the 20 physician or patient level. These data, 21 as illustrated below, are available on 22 Actiq prescribing by specialty and show 23 the volume and distribution of 24 prescribing of Actiq by specialists.</p>

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<p style="text-align: right;">Page 334</p> <p>1 Now, that first sentence is 2 contradictory to what we saw in the 3 marketing plan, where they actually could 4 break it down by specialty from the IMS 5 source data, correct?</p> <p>6 MR. DIAMANTATOS: Objection. 7 Form. Foundation.</p> <p>8 THE WITNESS: Again, I don't 9 know where -- how that data was 10 arrived at. They said IMS was 11 source. But the FDA can also 12 check with IMS.</p> <p>13 So I believe what we've told 14 them here was the truthful 15 information we have, which did 16 show -- you know, if you look 17 through it, it does show the use 18 in psychiatry -- you know, it does 19 mirror much of the information 20 that was in there.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. Right. But you're telling 23 the FDA that IMS does not provide any 24 conclusive information as to the</p>	<p style="text-align: right;">Page 336</p> <p>1 anesthesiology had back pain at 49 2 percent and other uses within that 3 specialty, right?</p> <p>4 MR. DIAMANTATOS: Objection. 5 Form. Foundation. Calls for 6 speculation.</p> <p>7 BY MR. CRAWFORD: 8 Q. Do you recall that document? 9 MR. DIAMANTATOS: Let me 10 finish my objections for the 11 record, please. 12 Objection. Form. 13 Foundation. Calls for 14 speculation.</p> <p>15 THE WITNESS: I do recall 16 it. I don't know exactly how they 17 did it or how that information 18 arrived. 19 I saw it. We read it 20 together. That's all I can tell 21 you.</p> <p>22 BY MR. CRAWFORD: 23 Q. That's fine. 24 So somehow the company did</p>
<p style="text-align: right;">Page 335</p> <p>1 diagnosis of each patient at the 2 patient -- physician or patient level. 3 Is that what you're 4 informing the FDA, right?</p> <p>5 A. That's what I was told. And 6 I really suggest that you talk to an IMS 7 person to say what's the truth, because I 8 don't --</p> <p>9 Q. An IMS person within the 10 company, right?</p> <p>11 A. No. I mean, in all 12 fairness, if you're investigating this, 13 you can go to the IMS, and the date when 14 this occurred, what was the ability of 15 IMS to get this -- obtain this data. I 16 don't know the answer. IMS could 17 objectively tell you that information.</p> <p>18 Q. Right. But the company 19 obtained it somehow, because we saw it in 20 the marketing plan, right?</p> <p>21 MR. DIAMANTATOS: Objection 22 to form.</p> <p>23 BY MR. CRAWFORD: 24 Q. Broke it down -- remember</p>	<p style="text-align: right;">Page 337</p> <p>1 get that data from somewhere, right? 2 MR. DIAMANTATOS: Objection. 3 Form. Calls for speculation.</p> <p>4 BY MR. CRAWFORD: 5 Q. Apparently, from the 6 document.</p> <p>7 MR. DIAMANTATOS: Objection. 8 Form. Foundation. Calls for 9 speculation.</p> <p>10 One second. 11 Go ahead.</p> <p>12 THE WITNESS: I know as much 13 as you do in this case.</p> <p>14 BY MR. CRAWFORD: 15 Q. So you did reference a chart 16 on the next page, and it breaks it down 17 by specialty, the prescribing. 18 So it's PCP -- that's 19 primary care providers, right? 20 A. Yes. 21 Q. And neuro is neurologists or 22 neurology, right? 23 A. Again, I know as much as 24 you. That's how I would interpret it.</p>

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1 Q. And onc would be oncology?		1 THE WITNESS: You know, all
2 A. That's how I'm interpreting		2 I can say is we're showing the FDA
3 it.		3 where the specialties are. I
4 Q. Psych, psychology, right?		4 don't know all the details of how
5 A. That's my interpretation.		5 that was arrived at.
6 Q. And PNAN, pain or		6 I don't know what else to
7 anesthesiology, is that those areas		7 say.
8 generally?		8 BY MR. CRAWFORD:
9 A. You know, I don't know		9 Q. We also saw from the
10 exactly. It sounds reasonable, from the		10 marketing plan that PCPs, primary care
11 way you said it.		11 providers, were above 20 percent as a
12 Q. So you're reporting to the		12 specialty, right?
13 FDA here the usage by these five		13 And that's what's reflected
14 specialty groups, plus others; is that		14 here, right?
15 correct?		15 A. Right. Okay. Yes.
16 A. That -- yes.		16 Q. So if that was above 15
17 Q. But when you do the 15		17 percent, why aren't -- since they are a
18 percent calculation, you're cutting it up		18 nontargeted group, why weren't they
19 much more when you try to analyze whether		19 reported in the report as being above the
20 a particular specialty went above 15		20 15 percent threshold where some type of
21 percent, right?		21 corrective action was taken pursuant to
22 MR. DIAMANTATOS: Objection.		22 9.1.2?
23 Form. Foundation.		23 A. You're saying psychiatry?
24 THE WITNESS: You know, I'd		24 Q. Right -- no, I'm talking
	Page 339	Page 341
1 have to look at the algorithm and		1 about PCP, primary care providers.
2 what was used. I really -- right		2 A. Was that in the -- I was
3 now is probably not the best time		3 trying to think of the SOP.
4 for me to analyze this.		4 Did they have PCPs in there?
5 I don't know how this was		5 Q. No, that was not -- as an
6 arrived at versus the other. In		6 untargeted -- as a targeted group, it
7 the next page there is the		7 wasn't and that's outside --
8 quarterly distribution by		8 A. I don't know -- I don't know
9 specialty. So there's the		9 how they identified target -- I don't
10 percentages.		10 know all the -- all those categories. So
11 I mean, we were totally		11 I don't know how they add that up to be,
12 forthcoming to the agency on the		12 this is a group or not.
13 off label and where the		13 And so I don't even know
14 specialties were.		14 where the PCP, if it comes in one group.
15 BY MR. CRAWFORD:		15 I'd have to look at the -- those tables
16 Q. Right. But you -- if, in		16 with all that. So I don't know how
17 fact, you had the data in your marketing		17 that's -- how they summarized PCPs.
18 plans in 2004 about the breakdown of		18 Q. Right. "They" meaning the
19 usage within a specialty, like for		19 sales department put that together?
20 anesthesiology pain, that isn't being		20 A. The marketing research.
21 forthcoming, then, if you tell them that		21 Q. Right. Marketing research.
22 IMS doesn't provide that data?		22 All right.
23 MR. DIAMANTATOS: Objection.		23 MR. CRAWFORD: Let's pull
24 Form. Argumentative.		24 627.

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<p>1 MR. JENSEN: Exhibit-20. 2 - - - 3 (Whereupon, Teva-Marchione 4 Exhibit-20, 5 TEVA_MDL_A_01582360-377, was 6 marked for identification.) 7 - - - 8 BY MR. CRAWFORD: 9 Q. These are the minutes of the 10 meeting -- we marked Exhibit-20, 11 TEVA_MDL_A_01582360. 12 These are the meetings of -- 13 the minutes that the FDA sent to you of 14 the July 14th meeting, correct? 15 A. Yes. 16 Q. And this is the one where 17 you submitted Exhibit-11, the packet, to 18 them, right? 19 A. Yes. 20 Q. So you attended this 21 meeting, correct? 22 A. Yes, I did. 23 Q. All right. And the 24 minutes -- the meeting objective of the</p>	<p>1 the objective. 2 BY MR. CRAWFORD: 3 Q. Fair enough. I understand. 4 Thank you. 5 It says, The agency is 6 concerned about the abuse and diversion 7 of Actiq and would like to understand the 8 steps Cephalon is taking to prevent abuse 9 and implementation of the risk management 10 program. Available data suggests 11 considerable off-label use of Actiq and 12 the agency would like to understand the 13 steps Cephalon is taking to discourage 14 such use and ensure that off-label 15 promotion is not occurring. 16 If we go to the end there, 17 Number 3, it says, The sponsor stated 18 that they would like a meeting with DDMAC 19 regarding concerns about the review 20 process for draft promotional materials. 21 What is DDMAC? 22 A. It's the division of the FDA 23 that is responsible for drug promotional 24 review.</p>
<p>1 FDA minutes state that, To get an update 2 from the sponsor on information related 3 to pediatric exposures, use, diversion, 4 misuse, overdose, death and off-label use 5 of Actiq and any noncompliance issues 6 that the sponsor is aware of related to 7 the risk management program 8 implementation of Actiq. 9 So you agree that was the 10 meeting objective as it's stated in that 11 paragraph, right? 12 A. From the FDA perspective, 13 yes. 14 Q. Okay. Was that the 15 company's perspective, too? 16 MR. DIAMANTATOS: Objection. 17 Form. 18 BY MR. CRAWFORD: 19 Q. If you know. 20 MR. DIAMANTATOS: Same 21 objection. Foundation. 22 THE WITNESS: I mean, it was 23 their meeting. So, usually, the 24 person who calls the meeting has</p>	<p>1 Q. And it says, DDMAC expressed 2 concerns about the information provided 3 at this meeting and in the background 4 materials regarding the sponsor's 5 promotional practices as they relate to 6 off-label use. And DDMAC recommended 7 further discussions on this issue. DDMAC 8 and the sponsor agreed to have a 9 subsequent meeting to discuss these 10 issues. 11 Post-meeting note. A 12 meeting between representatives from 13 DDMAC and Cephalon was held on August 14 30th, 2004. 15 Do you recall that meeting? 16 A. Yes, I do. 17 Q. And did you attend that 18 meeting? 19 A. Yes, I did. 20 Q. All right. So let's mark 21 the next exhibit, which is Document -- 22 well, let's mark Document 1753. 23 - - - 24 (Whereupon, Teva-Marchione</p>
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<p style="text-align: right;">Page 346</p> <p>1 Exhibit-21, 2 TEVA_MDL_A_08245587-590, was 3 marked for identification.) 4 - - - 5 MR. JENSEN: Exhibit-21. 6 MR. CRAWFORD: Give me one 7 second here. 8 All right. I think we're 9 missing the e-mail from this one. 10 It's on the screen, but we have -- 11 we don't have it printed. So 12 we're going to have to get it, the 13 e-mail part, printed and replaced 14 here. 15 BY MR. CRAWFORD: 16 Q. But it's just a short 17 e-mail. You're welcome to look at my 18 copy of the e-mail here, if you'd like. 19 MR. CRAWFORD: Let's 20 actually mark this. Here is the 21 actual exhibit. 22 MR. DIAMANTATOS: Can you 23 call out the Bates numbers, too, 24 and make sure you give me the full</p>	<p style="text-align: right;">Page 348</p> <p>1 Greg, Tracie and Victor. I'm not sure if 2 it was received. Could you just check 3 with Victor if he got it. If he did, the 4 others did too. If he didn't, please 5 call me. 6 I want to go to the 7 attachment here, which are the draft 8 meeting minutes from the August 30th 9 meeting, right? 10 Did you prepare these? 11 A. I believe I did, based upon 12 this. 13 Q. Do you know if these were 14 ever finalized, from Cephalon's 15 standpoint? 16 A. You know, I don't remember. 17 Q. Okay. All right. So you 18 indicate that you attended the meeting 19 with Ed Berg, the assistant general 20 counsel, right? 21 A. That's correct. 22 Q. And Andy Pyfer was there as 23 well, correct? 24 A. That's correct.</p>
<p style="text-align: right;">Page 347</p> <p>1 number? 2 MR. CRAWFORD: Right. 3 MR. DIAMANTATOS: Thank you. 4 MR. CRAWFORD: Let's do 5 that. And I don't want to give 6 you my boarding pass for United, 7 so I'll take that off here. 8 So the Bates number there is 9 TEVA_MDL_A_08245587. 10 Give that other document 11 back, and we'll mark this one 12 instead. 13 THE WITNESS: Sure. 14 MR. CRAWFORD: Thank you. 15 - - - 16 (Whereupon, a discussion off 17 the record occurred.) 18 - - - 19 BY MR. CRAWFORD: 20 Q. All right. There we go. 21 So this was an e-mail from 22 you to Frances Smith, cc'ing yourself, 23 draft DDMAC meeting minutes. Fran, I 24 sent the attachment to Ed, Bob R., Andy,</p>	<p style="text-align: right;">Page 349</p> <p>1 Q. And others from your 2 company. 3 You write -- or what's 4 written here is, Tom Abrams stated that 5 after reviewing the July 4th -- the July 6 14th, 2004 meeting package -- are they 7 referring here to the Exhibit-11 package? 8 A. That's my understanding. 9 Q. -- DDMAC has significant 10 concerns about the promotion of Actiq. 11 He stated that drug was approved under 12 Subpart H, due to its significant safety 13 concerns (i.e., it's dangerous and can 14 kill opioid-naive patients and children 15 at certain doses). FDA was concerned -- 16 or was concerns, it says -- about the 17 safety of the drug at the time of 18 approval and it is concerned now. FDA 19 wants to avoid the unsafe use of the 20 product. 21 So do you recall, at the 22 meeting, these concerns that DDMAC was 23 raising about the promotion of Actiq? 24 A. Vaguely.</p>

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<p style="text-align: center;">Page 350</p> <p>1 Q. Abrams stated that he feels 2 that Cephalon is not concerned about and 3 encourages the off-label use of the 4 product. He specifically mentioned that 5 Cephalon did not seem concerned about the 6 15 percent cutoff of the inappropriate 7 sales target.</p> <p>8 Do you see that?</p> <p>9 A. I do see that.</p> <p>10 Q. Do you recall that being 11 raised in the meeting?</p> <p>12 A. I don't remember.</p> <p>13 Q. Okay. And they're referring 14 here, at least what's written in the 15 draft minutes written by your company, to 16 the 9.1.2, 15 percent cutoff, right?</p> <p>17 MR. DIAMANTATOS: Objection. 18 Form. Foundation. Calls for 19 speculation.</p> <p>20 THE WITNESS: That's how I 21 would infer it. But, you know, I 22 can't say 100 percent.</p> <p>23 BY MR. CRAWFORD: 24 Q. All right. Down at the</p>	<p style="text-align: center;">Page 352</p> <p>1 So the FDA was concerned 2 about the targeting of doctors that were 3 outside of the intended targets, right? 4 MR. DIAMANTATOS: Objection 5 to form. Speculation.</p> <p>6 THE WITNESS: I mean, I 7 think it's clear how it's written 8 here.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Do you recall at the meeting 11 the FDA expressing concerns about how 12 doctors were targeted for promotion?</p> <p>13 A. I don't recall the details 14 of the meeting. I'm just -- you know, 15 I'm sure I captured what I thought down 16 here.</p> <p>17 Q. So when this was drafted, 18 this was intended to try to capture, as 19 best as possible, what transpired at the 20 meeting, right?</p> <p>21 A. That would be my 22 interpretation.</p> <p>23 Q. And then the last paragraph 24 says, Tom Abrams concluded this part of</p>
<p style="text-align: center;">Page 351</p> <p>1 bottom, it says, After that introduction, 2 Tom Abrams then provided more specific 3 comments.</p> <p>4 And then at the end of that 5 paragraph, he says, His interpretation is 6 that by sending letters for off-label 7 use, it infers that Cephalon sales reps 8 should be discouraging off-label use of 9 the product. By going to prescribers who 10 prescribe the product off label, Cephalon 11 is reinforcing off-label promotion.</p> <p>12 That is what is written 13 here, at least in this draft form, of 14 what transpired at the meeting, correct?</p> <p>15 A. Yes.</p> <p>16 Q. And then skipping down to 17 the small paragraph two below that, After 18 further discussions, Tom Abrams and Carol 19 Barstow stated that they believe if we 20 continue to promote and screen 21 physicians, as we do currently, we are 22 putting ourselves at risk. It was 23 recommended that we review our sales 24 training practices.</p>	<p style="text-align: center;">Page 353</p> <p>1 the discussion by stating that FDA is 2 looking at the total picture of sales and 3 promotion of the product. He stated that 4 our drug is under a lot of scrutiny 5 beyond FDA. There have been complaints 6 about the promotion of the product and 7 that DDMAC is monitoring this very 8 closely. He stated that they are 9 prepared to take action beyond NOV 10 letters and warning letters. He stated 11 that it is the responsibility of the 12 corporate compliance to investigate the 13 sales training and materials.</p> <p>14 So this is -- this seems 15 like a rather harsh assessment of the 16 promotional practices.</p> <p>17 Did this raise any kind of 18 concerns within the company, after this 19 August 30th meeting?</p> <p>20 MR. DIAMANTATOS: Objection. 21 Form.</p> <p>22 THE WITNESS: I mean, I 23 can't remember actions afterwards. 24 But, obviously, yes, it expressed</p>

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<p>1 concern.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. So he -- it sounds like --</p> <p>4 like they're ready to take action beyond</p> <p>5 letters and warning letters, that's what</p> <p>6 happened.</p> <p>7 And that means -- what type</p> <p>8 of actions does the FDA have the</p> <p>9 capability of taking in the regulatory</p> <p>10 framework beyond that?</p> <p>11 MR. DIAMANTATOS: Objection.</p> <p>12 Form.</p> <p>13 Go ahead.</p> <p>14 THE WITNESS: They didn't</p> <p>15 take any action. They didn't give</p> <p>16 us a warning letter. They didn't</p> <p>17 give us an NOV letter. And they</p> <p>18 took no action.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. They took no action against</p> <p>21 you?</p> <p>22 A. No.</p> <p>23 Q. Or the company?</p> <p>24 A. No.</p>	<p>1 Cephalon, correct?</p> <p>2 A. Yes.</p> <p>3 Q. And this appears to be the</p> <p>4 minutes of the August 30th meeting that</p> <p>5 the FDA is providing, right?</p> <p>6 A. That's correct.</p> <p>7 Q. And looking down here, under</p> <p>8 background, it says, Cephalon requested a</p> <p>9 follow-up meeting with DDMAC to discuss</p> <p>10 concerns regarding the review process for</p> <p>11 its promotional pieces. DDMAC agreed to</p> <p>12 meet with Cephalon and also stated that</p> <p>13 it would like to discuss various concerns</p> <p>14 DDMAC had regarding the promotion of</p> <p>15 Actiq, including concerns regarding</p> <p>16 information about Cephalon's promotion</p> <p>17 that was provided by Cephalon during the</p> <p>18 July 14th, 2004 joint division meeting</p> <p>19 and in Cephalon's briefing package for</p> <p>20 the July 14th, 2004 meeting.</p> <p>21 So DDMAC was -- obviously,</p> <p>22 that meeting did not go that well on the</p> <p>23 14th; they were pretty concerned about</p> <p>24 the off-label promotion in that meeting.</p>
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<p>1 Q. It just died after this?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Last paragraph, last</p> <p>4 sentence, DDMAC will provide their</p> <p>5 minutes and Cephalon can review those and</p> <p>6 provide comments and clarification to</p> <p>7 those minutes.</p> <p>8 So let's attach those</p> <p>9 minutes, which are 627.</p> <p>10 - - -</p> <p>11 (Whereupon, Teva-Marchione</p> <p>12 Exhibit-22,</p> <p>13 TEVA_MDL_A_01584978-986, was</p> <p>14 marked for identification.)</p> <p>15 - - -</p> <p>16 MR. CRAWFORD: Is that</p> <p>17 right? I'm sorry, 1691.</p> <p>18 MR. JENSEN: Exhibit-22.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. So are these the -- we've</p> <p>21 marked here Exhibit-22,</p> <p>22 TEVA_MDL_A_01584978.</p> <p>23 This is a letter from the</p> <p>24 FDA -- or DDMAC, rather, to you at</p>	<p>1 right?</p> <p>2 MR. DIAMANTATOS: Objection</p> <p>3 to form. Foundation. Calls for</p> <p>4 speculation. Argumentative.</p> <p>5 THE WITNESS: I mean, I</p> <p>6 think you can read it. It</p> <p>7 wasn't -- they weren't giving us a</p> <p>8 pat on the back. But they also</p> <p>9 pre-cleared all our promotion</p> <p>10 pieces. So they saw everything</p> <p>11 that we sent them.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. What do you mean they</p> <p>14 "pre-cleared" it?</p> <p>15 A. So under Subpart H, you have</p> <p>16 to send all of your promotion pieces to</p> <p>17 the FDA before you release it. So we did</p> <p>18 that. They gave us comments, and we</p> <p>19 incorporated. So they saw everything</p> <p>20 that we were promoting on.</p> <p>21 Q. When you submitted the</p> <p>22 materials to the -- to DDMAC or the FDA?</p> <p>23 A. No, DDMAC. DDMAC is a</p> <p>24 subset of FDA.</p>

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<p style="text-align: right;">Page 358</p> <p>1 Q. Did you have to get an 2 affirmative approval back to use it, or 3 was there, like, a 30-day period they 4 could comment and then you could use it?</p> <p>5 A. Yeah, within the 30 days -- 6 I think it was 30 days, they would give 7 us comments on the pieces.</p> <p>8 Q. Right.</p> <p>9 A. And we would review those 10 comments and revise the pieces 11 accordingly before we issued them.</p> <p>12 Q. And what if you got no 13 comment back at all, could you use the 14 piece after 30 days?</p> <p>15 A. We would always tell them 16 that, but we always waited.</p> <p>17 Q. Right. So you wouldn't even 18 use a piece until you got something back 19 from them, or were there instances where 20 there's a time period they have to get 21 back to you, and if they don't, you can 22 use it?</p> <p>23 A. I think --</p> <p>24 MR. DIAMANTATOS: Objection</p>	<p style="text-align: right;">Page 360</p> <p>1 THE WITNESS: That's what 2 they wrote in here.</p> <p>3 BY MR. CRAWFORD:</p> <p>4 Q. At least reflected in the 5 minutes?</p> <p>6 A. Yes.</p> <p>7 Q. Do you remember those 8 concerns being raised in the meeting?</p> <p>9 A. You know, in general.</p> <p>10 Q. So the concerns regarding 11 promotion here, it says, DDMAC expressed 12 significant concerns about the increasing 13 off-label use of Actiq, particularly in 14 light of the risk management plan that is 15 in effect for Actiq, which mandates that, 16 among other things, the company act to 17 prevent against improper patient 18 selection. DDMAC reminded Cephalon that 19 off-label promotion is illegal and, 20 especially with a drug with a risk 21 profile like Actiq, raises significant 22 public health concerns. As discussed 23 further below, DDMAC expressed concerns 24 that Cephalon's training and detailing</p>
<p style="text-align: right;">Page 359</p> <p>1 to form. 2 Go ahead.</p> <p>3 THE WITNESS: I think we 4 would always wait for comments.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. The discussion points.</p> <p>7 DDMAC's concerns regarding off-label use 8 of Actiq. The targeting criteria and 9 lack of screening for physicians called 10 upon by Cephalon sales force to promote. 11 Actiq training and detailing practices, 12 which inappropriately broaden the drug's 13 labeled indication. The eliciting of and 14 response of off-label inquiries regarding 15 Actiq. Minimalizing the fatal risk of 16 Actiq to children. And the promotional 17 use of disease awareness materials that 18 discuss conditions for which Actiq is not 19 indicated to treat.</p> <p>20 So those were DDMAC's 21 concerns coming into the meeting, right?</p> <p>22 MR. DIAMANTATOS: Objection</p> <p>23 to form. Foundation. Calls for 24 speculation.</p>	<p style="text-align: right;">Page 361</p> <p>1 practices appear to encourage the 2 off-label use of Actiq rather than 3 discourage it.</p> <p>4 So, again, was this a 5 concern that DDMAC expressed in this 6 meeting to Cephalon and its attendees?</p> <p>7 A. I believe, I mean, like, 8 being written in here, they expressed 9 that.</p> <p>10 Q. So these minutes, is there 11 anything in these minutes -- and take 12 your time to look at them if you want, we 13 can go through it, is there anything in 14 these minutes that seems inaccurate about 15 what DDMAC had expressed to Cephalon 16 during that meeting?</p> <p>17 And go ahead and take your 18 time if you need to look at that.</p> <p>19 A. Again, this is, obviously, 20 one-sided because they pre-cleared 21 everything.</p> <p>22 And the reason why we 23 initially asked for that -- this meeting, 24 which it said initially, was because they</p>

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<p>1 kept -- they kept reversing themselves on 2 their promotional review. And I said, 3 you're costing the company a 4 significant -- a lot of money for your 5 reversals.</p> <p>6 So I asked for prospective 7 meetings, on a quarterly basis, with 8 them, so we could review together so we 9 can get an understanding.</p> <p>10 And that came out of that 11 July -- I asked them for this in that 12 July 4th meeting. And this was the 13 follow-up.</p> <p>14 So I think it says here 15 that -- following the July -- Cephalon 16 requested a follow-up meeting to discuss 17 the concerns regarding the review process 18 for its promotional pieces.</p> <p>19 That's on the bottom, in the 20 background.</p> <p>21 So I asked for this meeting 22 because I was concerned about how they 23 kept reversing themselves. So I 24 understand -- they probably had</p>	<p>1 they -- they got to see all our pieces 2 before we had them printed.</p> <p>3 Q. Well, they're not talking -- 4 the FDA -- DDMAC's concerns are on the 5 second page at A.</p> <p>6 And I don't really see much 7 here about the promotional pieces, 8 although I think they did have a concern 9 about those at the meeting, correct?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Form.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. They had a concern about 14 promotional pieces at the meeting, is 15 that what you're saying?</p> <p>16 MR. DIAMANTATOS: Objection. 17 Form. Calls for speculation.</p> <p>18 THE WITNESS: I thought you 19 were just reading to me where they 20 were concerned about 21 promotional -- I mean, I'd have 22 to --</p> <p>23 BY MR. CRAWFORD: 24 Q. I'm looking at discussion</p>
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<p>1 legitimate concerns, but the FDA 2 pre-cleared all our promotion pieces.</p> <p>3 So I feel like they were 4 talking out both sides of their mouth, in 5 a sense.</p> <p>6 Q. So you said they reversed 7 themselves.</p> <p>8 Tell me what you mean by 9 "they reversed themselves."</p> <p>10 A. So in one -- in one piece 11 they would say, you have to -- you know, 12 you have to add this information, and 13 then the next -- the next time we would 14 add that information, we would put that 15 in for another piece in pre-clearance 16 with the information they wanted, and 17 they would tell us to take it out.</p> <p>18 So this went back and forth, 19 every single piece. So, you know, 20 they're not going to reflect in here 21 their faults, necessarily. But, I mean, 22 they pre-cleared everything, so I'm not 23 quite sure why they were as surprised, if 24 I should say, with the concerns. Because</p>	<p>1 points, A. It says, DDMAC's concerns 2 regarding -- the first is off-label use 3 of Actiq.</p> <p>4 They were more concerned 5 about the use. Remember, the staggering 6 use that the FDA brought up in the call, 7 prior to the July 14th meeting.</p> <p>8 So they are concerned about 9 off-label use, which is, you know, not 10 directly promotional materials, they were 11 just concerned about the off-label use, 12 right?</p> <p>13 MR. DIAMANTATOS: Objection. 14 Form. Calls for speculation.</p> <p>15 THE WITNESS: I'm sorry, 16 when you were reading something, 17 it sounded very distinctly like 18 they were concerned about the 19 pieces.</p> <p>20 BY MR. CRAWFORD: 21 Q. They may have been concerned 22 about the pieces.</p> <p>23 But they are -- also, that 24 wasn't the whole subject of the meeting.</p>

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<p>1 They were concerned about the off-label 2 use of Actiq, right? 3 A. Uh-huh. 4 Q. Do you agree? 5 A. Yes. 6 Q. Okay. And they were 7 concerned about the targeting criteria 8 used for targeting doctors with regard to 9 Actiq, right?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Form.</p> <p>12 THE WITNESS: That's what 13 it --</p> <p>14 MR. DIAMANTATOS: Calls for 15 speculation.</p> <p>16 THE WITNESS: That's what it 17 says here.</p> <p>18 BY MR. CRAWFORD: 19 Q. Right. A promotional piece 20 wouldn't necessarily clue them in to the 21 targeting practices that raises these 22 concerns, right?</p> <p>23 MR. DIAMANTATOS: Objection 24 to form. Calls for speculation.</p>	<p>1 couldn't break down what it was 2 prescribed for within the specialty. 3 MR. DIAMANTATOS: Objection. 4 Form. Mischaracterizes -- 5 BY MR. CRAWFORD: 6 Q. Right. Remember on Page 7 8 -- 8 MR. DIAMANTATOS: Objection. 9 Form.</p> <p>10 BY MR. CRAWFORD: 11 Q. -- of your letter? 12 MR. DIAMANTATOS: Objection. 13 Form. Mischaracterizes testimony. 14 THE WITNESS: I'd have to go 15 through here further. But I think 16 we were pretty clear that there 17 was significant off label, and I 18 thought we gave percentages. It's 19 been -- obviously, it's been a 20 while since I --</p> <p>21 BY MR. CRAWFORD: 22 Q. Why don't you take a look 23 and find me the off-label disclosure in 24 that letter?</p>
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<p>1 Foundation. 2 THE WITNESS: That's true. 3 But the quarterly reports told -- 4 inferred where the targeting was. 5 So we were very up front. 6 We were very communicative. There 7 was nothing that we were hiding. 8 And this huge package, it was very 9 specific about the off label and 10 what we were targeting.</p> <p>11 BY MR. CRAWFORD: 12 Q. Well, on off label, it 13 didn't reveal that 50 percent, 14 approximately, use among 15 anesthesiologists was for back pain. 16 A. I mean, I can't remember the 17 page --</p> <p>18 MR. DIAMANTATOS: Objection. 19 Form.</p> <p>20 THE WITNESS: I'd have to go 21 through here. But we were pretty 22 clear, I thought.</p> <p>23 BY MR. CRAWFORD: 24 Q. I think you told them you</p>	<p>1 But this is in the July 12th 2 letter you told them about it, right? 3 A. The meeting -- the meeting 4 package? 5 Q. Yes. 6 A. Yes. 7 Q. You did not tell them about 8 it in the quarterly reports, though? All 9 the high off-label use, you didn't 10 disclose that?</p> <p>11 MR. DIAMANTATOS: Objection. 12 Form. Vague. Asked and answered. 13 THE WITNESS: We complied 14 with everything they asked for in 15 the quarterlies. And there's -- 16 in there we talk about off-label 17 letters and everything. 18 Again, I'd have to -- it's 19 been a while for the specifics. 20 But we even showed a graph, I 21 thought. 22 Actiq off-label counts and 23 patient exposure. It does show a 24 diagram, this is off-label counts</p>

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<p>1 versus patient exposure. This is 2 a very thick document. 3 But we were very 4 forthcoming. Counts, letters, 5 patients' exposure. 6 It would take me forever to 7 go through this.</p> <p>8 BY MR. CRAWFORD: 9 Q. Well, why don't you grab 10 Exhibit-9, which is your quarterly 11 report, and show me where you're 12 disclosing the level of off-label use in 13 that report?</p> <p>14 MR. DIAMANTATOS: Are you 15 withdrawing the question with 16 regard to Exhibit-11, or are you 17 going to give her an opportunity 18 to find what you asked her to 19 find?</p> <p>20 MR. CRAWFORD: I thought she 21 said she couldn't find it.</p> <p>22 MR. DIAMANTATOS: That's not 23 what she said. She said it would 24 take her time to find it.</p>	<p>1 extent of off-label use of Actiq? 2 MR. DIAMANTATOS: Objection. 3 Form. Argumentative. Asked and 4 answered. The document will speak 5 for itself. 6 MR. CRAWFORD: I wanted her 7 view that if it is -- 8 MR. DIAMANTATOS: You didn't 9 want it on Exhibit-11. 10 MR. CRAWFORD: I got it 11 already. I just had her point it 12 out. 13 THE WITNESS: So there's 14 no -- no specific section that 15 says what's your off-label use. 16 We had a report on all these 17 other -- so, I mean, we talked 18 about all the off-label letters we 19 got when we heard about it. 20 There isn't anything in here 21 to specifically ask, what's your 22 percent of off label? BY MR. CRAWFORD: Q. Well, okay. On Page 11,</p>
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<p>1 MR. CRAWFORD: I'll withdraw 2 it.</p> <p>3 MR. DIAMANTATOS: Why don't 4 you note for the record how large 5 Exhibit-11 is, by listing the 6 Bates stamp? That's something you 7 failed to do in comparison to what 8 the other exhibits are.</p> <p>9 MR. CRAWFORD: I only raised 10 it because she said, counsel, that 11 we told them about all the 12 off-label use in the report. 13 So I asked her -- it is a 14 large report, I agree. So I'll 15 withdraw the question.</p> <p>16 BY MR. CRAWFORD: 17 Q. Let's go to your quarterly 18 report at Exhibit-9. 19 The document will speak for 20 itself, whatever is disclosed in there is 21 disclosed in there. 22 So let's go to Exhibit-9. 23 And if you could -- was Cephalon 24 forthcoming in this report about the</p>	<p>1 9.1, there's a section called, Off-label 2 usage, right? 3 A. Let me see. 9.1. 4 I'm sorry, I'm looking at 5 Exhibit-7. 6 MR. DIAMANTATOS: Exhibit-9. BY MR. CRAWFORD: Q. Exhibit-9, I'm sorry. A. This is the RiskMAP. I'm sorry, what page was it? Q. Page 11. There's a section on off-label usage, and there's no disclosures in there about the extent of the off-label usage or anything being done. A. So what it tells you that we need to do is, initial instance of off label -- it doesn't ask for numbers. It says we need to send a letter from our global product safety, which we did. Q. And then 9.1.2 is missing. That section is missing, right? MR. DIAMANTATOS: Objection.</p>

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<p style="text-align: right;">Page 374</p> <p>1 Form.</p> <p>2 THE WITNESS: And that's</p> <p>3 about the percentage. That was</p> <p>4 about the 15 percent.</p> <p>5 So that's about the</p> <p>6 targeting. So that's not</p> <p>7 necessarily about how much -- you</p> <p>8 know, like, it doesn't say, give</p> <p>9 your percentage of off label.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. Let's go back to Exhibit-22.</p> <p>12 So I think my question was</p> <p>13 here, I mean, these are minutes from the</p> <p>14 FDA of DDMAC's concerns that are outlined</p> <p>15 in Points 1, 2, 3 and 4 through 6. They</p> <p>16 express concerns here.</p> <p>17 Were these concerns -- does</p> <p>18 this accurately reflect, in your view,</p> <p>19 the concerns that DDMAC raised at this</p> <p>20 meeting that you attended?</p> <p>21 A. I'm going to have to read</p> <p>22 it.</p> <p>23 Q. Sure.</p> <p>24 A. Give me a couple of minutes.</p>	<p style="text-align: right;">Page 376</p> <p>1 are already receiving and who are</p> <p>2 tolerant to opioid therapy for their</p> <p>3 underlying persistent cancer pain.</p> <p>4 Again, was that -- was this</p> <p>5 type of targeting concern raised at the</p> <p>6 meeting, that you recall?</p> <p>7 MR. DIAMANTATOS: Objection.</p> <p>8 Form. Assumes facts.</p> <p>9 THE WITNESS: I believe it</p> <p>10 was. But I'm not seeing -- I'm</p> <p>11 just trying to see -- we obviously</p> <p>12 responded to in the meeting.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Right. But they give you --</p> <p>15 A. The company takes the law</p> <p>16 applying the -- very seriously. Cephalon</p> <p>17 confirms that it does target physicians</p> <p>18 in various specialties by their opioid</p> <p>19 prescribing practices, regardless of</p> <p>20 whether they treat cancer patients or</p> <p>21 cancer pain. Specifically, physicians</p> <p>22 who write at least 24 opioid</p> <p>23 prescriptions in six months are targeted</p> <p>24 for a sales call by Cephalon sales</p>
<p style="text-align: right;">Page 375</p> <p>1 Q. Yes.</p> <p>2 A. You started with 2, did you?</p> <p>3 Q. Yeah. And actually I can go</p> <p>4 through the points that I -- that I'm</p> <p>5 really concerned about or want to raise</p> <p>6 with regard to whether they raise these</p> <p>7 concerns.</p> <p>8 A. Okay.</p> <p>9 Q. So 2 -- I think we went</p> <p>10 through 1.</p> <p>11 2, DDMAC expressed concerns</p> <p>12 that, as indicated by Cephalon's briefing</p> <p>13 package for and presentation at the July</p> <p>14 14th, 2004 meeting, the company targets</p> <p>15 physicians for Actiq promotion purely</p> <p>16 based on the number of opioid</p> <p>17 prescriptions they write, and the company</p> <p>18 is making no effort to screen these</p> <p>19 targeted physicians to determine whether</p> <p>20 they treat cancer patients and, thus,</p> <p>21 would be appropriate to be detailed on</p> <p>22 Actiq, given its limited indications,</p> <p>23 i.e., management of breakthrough cancer</p> <p>24 pain, in patients with malignancies who</p>	<p style="text-align: right;">Page 377</p> <p>1 representative. The company believes</p> <p>2 that it's a good idea to call on</p> <p>3 physicians who do not treat breakthrough</p> <p>4 cancer pain, based on belief that such</p> <p>5 calls can encourage these physicians to</p> <p>6 treat these conditions, should they see</p> <p>7 it in their practice. The company also</p> <p>8 stated its belief that a physician did</p> <p>9 not need to routinely see cancer patients</p> <p>10 to be an appropriate target for an Actiq</p> <p>11 sales call. Cephalon also confirmed that</p> <p>12 its sales representatives will make</p> <p>13 repeated calls to target physicians who</p> <p>14 are not using Actiq for the treatment of</p> <p>15 breakthrough cancer pain. Cephalon also</p> <p>16 indicated its belief that in addition to</p> <p>17 communications from its medical</p> <p>18 department, sending its sales</p> <p>19 representatives to call on physicians who</p> <p>20 are using Actiq off label was an</p> <p>21 effective way of communicating important</p> <p>22 risk information to these physicians and</p> <p>23 did not encourage off-label use, though</p> <p>24 they would consider DDMAC's comments on</p>

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<p style="text-align: right;">Page 378</p> <p>1 the issue.</p> <p>2 Cephalon also noted it's</p> <p>3 belief that the RiskMAP, RMP, does not</p> <p>4 require the company to discourage</p> <p>5 off-label use of Actiq. While noting</p> <p>6 that it does not promote Actiq off label,</p> <p>7 Cephalon stated its belief that pain in</p> <p>8 general is an underrated medical need and</p> <p>9 that Actiq can be used safely and</p> <p>10 effectively for other uses than</p> <p>11 breakthrough cancer pain. The company</p> <p>12 will be pursuing a broadened indication</p> <p>13 for the drug.</p> <p>14 Q. And doesn't DDMAC address</p> <p>15 that argument in the paragraph above?</p> <p>16 They state here, Actiq's</p> <p>17 briefing package, at Page 598, in</p> <p>18 comments made by Cephalon at the July</p> <p>19 14th meeting, indicate that Cephalon</p> <p>20 sales representatives are calling on</p> <p>21 physicians who are not treating BTCP,</p> <p>22 breakthrough cancer pain, and who are not</p> <p>23 prescribing Actiq already. This is</p> <p>24 especially concerning, as many of the</p>	<p style="text-align: right;">Page 380</p> <p>1 away. So I don't know how one can</p> <p>2 interpret that, other than, you know, we</p> <p>3 were -- we expressed what our issues</p> <p>4 were, and, you know, it's kind of on</p> <p>5 either side.</p> <p>6 And, you know, I think</p> <p>7 that -- you know, I think that paragraph</p> <p>8 speaks for itself.</p> <p>9 Q. Didn't Cephalon pay a \$50</p> <p>10 million fine, criminal fine, for</p> <p>11 promoting Actiq and other drugs off label</p> <p>12 during this period?</p> <p>13 MR. DIAMANTATOS: Objection.</p> <p>14 Form. Foundation.</p> <p>15 Go ahead and answer the</p> <p>16 question.</p> <p>17 THE WITNESS: To be honest,</p> <p>18 I thought it was -- I thought it</p> <p>19 was for Provigil. I didn't know</p> <p>20 if Actiq was part of the --</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. It was Gabitril, Provigil</p> <p>23 and Actiq.</p> <p>24 A. And that was not -- I mean,</p>
<p style="text-align: right;">Page 379</p> <p>1 targeted specialty areas, such as</p> <p>2 physical medicine specialists, do not</p> <p>3 routinely treat cancer patients. There</p> <p>4 does not appear to be any reason -- let</p> <p>5 me back up.</p> <p>6 The physical medicine</p> <p>7 specialties were -- was a specialty group</p> <p>8 that was designated as a targeted group,</p> <p>9 and so, therefore, was not being</p> <p>10 monitored for the 15 percent or for the</p> <p>11 off-label promotion in the SOPs, right?</p> <p>12 A. You know, I can't remember</p> <p>13 exactly. But the rationale for why they</p> <p>14 were doing what -- what they -- what were</p> <p>15 targeted to do is in this second</p> <p>16 paragraph.</p> <p>17 So I believe -- I'm not</p> <p>18 denying that DDMAC feels that way. I</p> <p>19 think we have -- I think, Cephalon had a</p> <p>20 very logical rationale for why we</p> <p>21 promoted, to make sure it was safe.</p> <p>22 And subsequently, we never</p> <p>23 got a warning letter. We never got an</p> <p>24 NOV. And they never took the approval</p>	<p style="text-align: right;">Page 381</p> <p>1 that was not -- FDA did -- again, that's</p> <p>2 what my hat is, the regulatory FDA hat, I</p> <p>3 have never heard anything back from the</p> <p>4 FDA, per se, that we were -- after that,</p> <p>5 that they held anything up or NOVs or</p> <p>6 anything.</p> <p>7 Q. So you never heard that</p> <p>8 Cephalon had pleaded guilty to off-label</p> <p>9 marketing of Actiq and Provigil and</p> <p>10 Gabitril?</p> <p>11 MR. DIAMANTATOS: Objection</p> <p>12 to form. That mischaracterizes</p> <p>13 the witness's answer.</p> <p>14 Go ahead and answer.</p> <p>15 THE WITNESS: I'm talking --</p> <p>16 I'm -- my responsibility was my</p> <p>17 communications with the FDA, and</p> <p>18 how they interpreted.</p> <p>19 We never had the product</p> <p>20 withdrawn or an NOV or warning</p> <p>21 letter from the FDA. So I'm</p> <p>22 just -- and I hear what you're</p> <p>23 saying. I'm not trying to deny</p> <p>24 it. I'm just saying, this was my</p>

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<p style="text-align: right;">Page 382</p> <p>1 focus. 2 BY MR. CRAWFORD: 3 Q. Right. And I'm just trying 4 to understand if you had ever heard that 5 Actiq was part of the -- Actiq off-label 6 marketing by Cephalon was part of the 7 guilty plea that they entered in 2008? 8 A. You know, my recollection, I 9 thought it was just Provigil. I 10 really -- I'm not trying to be -- 11 Q. I know. 12 But you don't remember it 13 being Actiq? 14 A. No, I actually did not. To 15 be honest, I didn't. 16 Q. Fair enough. 17 They do -- and this is in 18 response to the paragraph you read. They 19 say, There does not appear to be any 20 reason for these sales calls to be, other 21 than to promote Actiq outside its labeled 22 indication. And the fact that off-label 23 prescriptions have increased in such 24 specialty areas seems to add validity to</p>	<p style="text-align: right;">Page 384</p> <p>1 Q. In your view, would 90 2 percent off-label use be staggering? 3 MR. DIAMANTATOS: Objection 4 to form. Assumes facts. 5 Argumentative. Asked and 6 answered. 7 THE WITNESS: I don't know 8 if I would -- I probably -- 9 staggering. 10 I don't know. I guess -- 11 it's definitely high, but there's 12 a lot of people -- I don't know. 13 Yes, it's a high level. 14 BY MR. CRAWFORD: 15 Q. But the intent of the 16 RiskMAP was to try to prevent off-label 17 prescribing, right? 18 MR. DIAMANTATOS: Objection. 19 Form. Foundation. Calls for 20 speculation. Asked and answered. 21 THE WITNESS: That was one 22 of the three intentions of the 23 RiskMAP. 24 BY MR. CRAWFORD:</p>
<p style="text-align: right;">Page 383</p> <p>1 this conclusion. 2 So you don't deny that 3 there's staggering off-label use of the 4 product at this time? 5 MR. DIAMANTATOS: Objection. 6 Form. Argumentative. 7 THE WITNESS: I -- 8 MR. DIAMANTATOS: 9 Foundation. 10 Go ahead. 11 THE WITNESS: I will agree 12 there was off-label use at the 13 time, yes. 14 BY MR. CRAWFORD: 15 Q. But would you agree it was 16 staggering? 17 MR. DIAMANTATOS: Objection. 18 Form. 19 Go ahead. 20 THE WITNESS: How does one 21 define that? I don't know. I'm 22 being open, I'm saying, yes, I 23 agree there was off-label use. 24 BY MR. CRAWFORD:</p>	<p style="text-align: right;">Page 385</p> <p>1 Q. And then, and this is more 2 specific to what you read, In addition, 3 DDMAC expressed concerns regarding 4 Cephalon's stated reason at the July 14th 5 meeting for sending sales representatives 6 to call upon physicians who were clearly 7 using Actiq off label, namely, to provide 8 risk information to help ensure safe use 9 of the drug. While DDMAC acknowledged 10 how important it is that these physicians 11 receive information from Cephalon 12 regarding the serious risks associated 13 with using this drug, as per the RiskMAP, 14 DDMAC questioned whether having a 15 promotional arm of the company, the sales 16 force, repeatedly call on these 17 physicians was the most effective way of 18 communicating risk information and 19 whether it would not also potentially 20 encourage -- encourage rather than 21 discourage the off-label uses, which 22 would violate the principles of the 23 RiskMAP. 24 So DDMAC clearly disagreed</p>

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<p style="text-align: right;">Page 386</p> <p>1 with your rationale of sending these 2 sales representatives -- or the company's 3 rationale of sending these sales 4 representatives to doctors who, in 5 general, didn't treat cancer patients, to 6 try to talk to them about risk 7 information. They thought it should come 8 from a nonpromotional arm.</p> <p>9 Do you agree that that was 10 the position they took at the meeting?</p> <p>11 MR. DIAMANTATOS: Objection. 12 Form. Foundation. Calls for 13 speculation. Argumentative.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. You attended this meeting, 16 right? 17 A. Right. 18 I understand -- I understand 19 the rationale, yes.</p> <p>20 Q. Okay. And then, 3, DDMAC 21 expressed concern that Cephalon, as 22 indicated in the briefing package for the 23 July 14th, 2004 meeting, see Page 191, 24 and in its presentation at the meeting,</p>	<p style="text-align: right;">Page 388</p> <p>1 But -- so we did have some 2 clarifications to these minutes 3 after the fact. So I just don't 4 remember the details.</p> <p>5 BY MR. CRAWFORD: 6 Q. And then just skipping ahead 7 to 6, it says, DDMAC expressed questions 8 and concerns regarding how Cephalon's 9 sales force is using disease awareness 10 materials that discuss broad conditions, 11 such as BTP, that would go beyond Actiq's 12 indicated use. 13 Is that, again, another 14 concern they expressed at this meeting?</p> <p>15 MR. DIAMANTATOS: Objection. 16 Form. 17 THE WITNESS: Again, I don't 18 remember specifically. But I'm 19 deducing, because it's written 20 here.</p> <p>21 BY MR. CRAWFORD: 22 Q. So, in summary -- and there 23 are other points, but in summary, they 24 state, DDMAC summarized that it is</p>
<p style="text-align: right;">Page 387</p> <p>1 is instructing its sales force to open 2 sales calls in a manner that fails to 3 focus on Actiq's limited indication and 4 instead focuses on the physician's 5 treatment of breakthrough pain in 6 general, thus inappropriately broadening 7 physicians' perceptions of the drug's use 8 to the treatment of all forms of BTP 9 rather than BTCP in the indicated 10 populations. 11 So, again, was this another 12 concern that DDMAC expressed in the 13 meeting?</p> <p>14 MR. DIAMANTATOS: Objection 15 to form and foundation. Calls for 16 speculation.</p> <p>17 THE WITNESS: I mean, just 18 by -- I mean, this sounds correct. 19 It's in the minutes. 20 We did not object -- we 21 added a document in the file to 22 these minutes, if I can remember. 23 And I can't remember what they -- 24 I don't know if you can find that.</p>	<p style="text-align: right;">Page 389</p> <p>1 concerned -- this is on the last page. 2 A. Okay. The very last? 3 Q. Yes, very last page under 4 summary. 5 A. Okay. 6 Q. I just want to look at that 7 first paragraph there under summary. 8 A. Where it says, DDMAC 9 summarized? That one? 10 Q. Yes. 11 DDMAC summarized that it is 12 concerned about the promotion of Actiq 13 and is monitoring this promotion very 14 closely. 15 So DDMAC was, in fact, 16 intending to monitor this? It wasn't 17 going to just drop it, right? 18 MR. DIAMANTATOS: Objection. 19 Calls for speculation. Form. 20 BY MR. CRAWFORD: 21 Q. Is that what they conveyed 22 at the meeting? 23 A. That's what they conveyed. 24 By default, they pre-cleared</p>

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<p>1 all the promotional pieces. So by 2 default, they were doing that anyway. 3 Q. So after this time, do you 4 remember DDMAC doing anything about this, 5 or did it just drop?</p> <p>6 MR. DIAMANTATOS: Objection. 7 Form.</p> <p>8 THE WITNESS: We never got 9 any -- anything else after this.</p> <p>10 Again, the only other 11 communication was I sent, I 12 thought, a clarifying letter, to 13 the best of my knowledge. I 14 can't -- maybe I'm misinterpreting 15 because there were so many 16 meetings, but -- so I think we 17 expressed some clarification on 18 our part.</p> <p>19 But we never got an NOV or a 20 warning letter after this.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. Okay. It does say, DDMAC 23 also noted that FDA is prepared to take 24 whatever action is necessary to address</p>	<p>1 interpretation. We never got 2 anything that said that we weren't 3 complying with the law from the 4 FDA.</p> <p>5 BY MR. CRAWFORD: 6 Q. All right. 7 MR. CRAWFORD: Let's mark 8 the next few exhibits.</p> <p>9 MR. DIAMANTATOS: If you're 10 moving on to another exhibit, 11 maybe it's time to take a break. 12 We've been at it almost an hour 13 and-a-half.</p> <p>14 MR. CRAWFORD: We can do 15 that.</p> <p>16 VIDEO TECHNICIAN: Going off 17 the record at 4:03 p.m. - - - 19 (Whereupon, a brief recess 20 was taken.) - - -</p> <p>22 VIDEO TECHNICIAN: Back on 23 the record at 4:17 p.m.</p> <p>24 BY MR. CRAWFORD:</p>
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<p>1 any violations and ensure that Cephalon 2 complies with the law and that the public 3 health is protected. Cephalon should 4 also be aware that DDMAC has received 5 complaints about its promotion, and that 6 it is under scrutiny by others who are 7 concerned about the potential for harm to 8 the public health from inappropriate use 9 of Actiq. Cephalon is strongly advised 10 to take whatever steps are necessary to 11 ensure that it is in compliance with the 12 law.</p> <p>13 So they wanted you to take 14 steps to comply with the law.</p> <p>15 Did you have to wait for 16 them to keep pushing you or prompting you 17 to do it, or would you take steps -- was 18 the company going to take steps to comply 19 with the law?</p> <p>20 MR. DIAMANTATOS: Objection. 21 Form. Foundation. Calls for 22 speculation. Argumentative. 23 Go ahead and answer. 24 THE WITNESS: So it's an</p>	<p>1 Q. We marked three of the next 2 exhibits, 23, 24 and 25. - - - 4 (Whereupon, Teva-Marchione 5 Exhibit-23, 6 TEVA_MDL_A_07424105-109, was 7 marked for identification.) - - - 9 (Whereupon, Teva-Marchione 10 Exhibit-24, 11 TEVA_MDL_A_00267691-694, was 12 marked for identification.) - - - 14 (Whereupon, Teva-Marchione 15 Exhibit-25, 16 TEVA_MDL_A_01583546-550, was 17 marked for identification.) - - - 19 THE WITNESS: Thank you. 20 BY MR. CRAWFORD: 21 Q. 23 -- 22 MR. DIAMANTATOS: Sorry, I 23 think I have -- 24 and 25. 24 THE WITNESS: Thank you.</p>

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<p style="text-align: right;">Page 394</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. Exhibit-23, if you look at 3 the last page, it's a fax cover page, is 4 a September 29th, 2004 fax from DDMAC to 5 Tracie Parker.</p> <p>6 That was your person who 7 reported to you, correct?</p> <p>8 A. That's correct.</p> <p>9 Q. Okay. And it's 10 TEVA_MDL_A_07424105.</p> <p>11 And then we've also marked 12 as Exhibit-24 a letter from DDMAC to Ms. 13 Parker there at Cephalon regulatory 14 affairs. That's dated November 24, 2004.</p> <p>15 And then Exhibit-25 is a 16 fax, again, from DDMAC to you, Ms. 17 Marchione, dated November 29th, 2005.</p> <p>18 So these are three DDMAC 19 letters written with regard to the 20 submission of promotional materials 21 Cephalon made to DDMAC regarding Actiq, 22 correct?</p> <p>23 A. To clarify, it's draft 24 promotion. This was part of the</p>	<p style="text-align: right;">Page 396</p> <p>1 review process, before and after. Every 2 time we sent any piece that ever went 3 out, we got one of these letters.</p> <p>4 Q. Right. But these three are 5 pointing out problems with these pieces, 6 aren't they?</p> <p>7 A. There --</p> <p>8 MR. DIAMANTATOS: Objection 9 to form.</p> <p>10 Go ahead.</p> <p>11 THE WITNESS: Problems, 12 maybe, is the wrong word.</p> <p>13 But this is the whole point 14 that I was saying, is we would get 15 these types of -- so every piece 16 we sent, we would get a letter 17 like this. And then, like, the 18 next piece would then reverse it.</p> <p>19 So these are -- this is just 20 a routine type of review. And 21 they always gave us comments, one 22 way or the other. So this wasn't 23 something that was out in the 24 market that we were distributing.</p>
<p style="text-align: right;">Page 395</p> <p>1 pre-clearance process.</p> <p>2 Q. Right. So DDMAC was getting 3 back to you and providing criticisms of 4 those materials and asking Cephalon to 5 correct them, correct?</p> <p>6 MR. DIAMANTATOS: Objection 7 to form.</p> <p>8 THE WITNESS: Or to revise 9 them.</p> <p>10 Again, it wasn't -- these 11 pieces weren't out in the public 12 at all. These were just draft 13 that went to the FDA for 14 pre-clearance.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Right. So this -- all three 17 letters come after the August 30th 18 meeting, following up with your meeting 19 with DDMAC, where DDMAC was coming to you 20 explaining why these materials you were 21 proposing using for Actiq were improper, 22 right?</p> <p>23 A. Right. But we have -- just 24 to be clear, we have these throughout the</p>	<p style="text-align: right;">Page 397</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. Right. So each of these 3 letters they state, up near the 4 beginning -- so let's take Exhibit-23, as 5 an example, they state, Since many claims 6 and representations are similar or 7 closely related, DDMAC's comments on a 8 particular claim or representation apply 9 to similar claims or representations in 10 these and future promotional materials 11 for Actiq.</p> <p>12 Right? So they were trying 13 to teach you how to -- how to properly 14 prepare these materials, right?</p> <p>15 MR. DIAMANTATOS: Objection 16 to form. Speculation.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: So we're -- 19 not teaching, but they're 20 saying -- this was my concern with 21 the agency, was so they say, okay, 22 for the future, you have to do 23 this.</p> <p>24 Then we would get another</p>

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<p style="text-align: right;">Page 398</p> <p>1 piece that would completely 2 reverse it, and say in the future 3 you have to change these pieces. 4 It was costing us extremely -- you 5 know, a large sum of money, 6 because every time they kept 7 reversing their positions.</p> <p>8 So these are their judgments 9 on draft pieces. When we would 10 get these comments, we would then 11 take our draft, revise them, based 12 upon -- to make sure they were in 13 compliance. And then that would 14 be, then, the final piece.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. Correct.</p> <p>17 So they're telling you 18 what's wrong with the pieces, and you're 19 going back and correcting them and 20 re-submitting them?</p> <p>21 A. That correct.</p> <p>22 Q. And their intent is, in 23 telling you this, that you should apply 24 their comments to future promotional</p>	<p style="text-align: right;">Page 400</p> <p>1 Q. So this first letter, dated 2 September 29th, that comes about a month 3 after -- less than a month after your 4 meeting with them, right?</p> <p>5 A. I guess --</p> <p>6 Q. August 30th meeting, right?</p> <p>7 A. Okay. Yep.</p> <p>8 Q. So they are giving you -- 9 they're following up on that meeting and 10 telling you what's -- what the problems 11 are with your promotional materials, 12 right?</p> <p>13 MR. DIAMANTATOS: Objection 14 to form. Speculation.</p> <p>15 THE WITNESS: No.</p> <p>16 MR. DIAMANTATOS: 17 Argumentative.</p> <p>18 THE WITNESS: That's not 19 what's happening.</p> <p>20 So this started -- this is 21 just a normal review process. 22 It's nothing to do, necessarily, 23 with that meeting.</p> <p>24 We had this review process</p>
<p style="text-align: right;">Page 399</p> <p>1 materials regarding Actiq, right? 2 A. That's correct.</p> <p>3 MR. DIAMANTATOS: Objection 4 to form. Speculation.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. They say that in the first 7 paragraph here, up above, Since many 8 claims and representations are similar or 9 closely related, DDMAC's comments on a 10 particular claim or representation apply 11 to similar claims or representations in 12 these and future promotional materials 13 for Actiq.</p> <p>14 Right?</p> <p>15 A. That's correct.</p> <p>16 Q. And that's -- they state 17 that again on Exhibit-24, right below the 18 bullet points, right?</p> <p>19 A. Yes.</p> <p>20 Q. And then Exhibit-25, they're 21 stating it again in that first -- the 22 last sentence of that paragraph, 23 underneath the bullet points, right?</p> <p>24 A. That's correct.</p>	<p style="text-align: right;">Page 401</p> <p>1 going on for the whole -- for the 2 whole lifecycle of Actiq. And we 3 will get these kind of comments -- 4 even though the timing may be 5 such, but these were -- this is a 6 common -- this is how they write 7 these letters. It's just giving 8 you the perspective of how they 9 want these draft pieces to be 10 revised.</p> <p>11 So this is -- we have 12 maybe -- probably 100 of these, or 13 something. So every time we went 14 to put a promotion piece out, we'd 15 have to get it pre-cleared.</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. Okay. So this Exhibit-23, 18 they talk about unsubstantiated 19 comparative claims, lack of important 20 contextual information, misleading 21 presentation of information, 22 overstatement of efficacy.</p> <p>23 Are these common comments 24 made in the past about -- prior to this</p>

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<p>1 letter, about Actiq promotional materials 2 or draft ones that were provided to them?</p> <p>3 MR. DIAMANTATOS: Objection 4 to form.</p> <p>5 THE WITNESS: This is how 6 they -- this is how they kind of 7 talk when they reviewed the 8 documents. So it's -- it's, you 9 know, this is how they tell you to 10 change things.</p> <p>11 And they always have to -- 12 they always have to support it in 13 context of the regulations. And 14 so they'll say, you know, it's 15 overstatement or whatever. So 16 they're trying to have you change 17 something.</p> <p>18 But this is what 19 pre-clearance is all about. And 20 Fentora was breakthrough -- our 21 subsequent approved product that 22 the FDA didn't have any problem, 23 we had the same types of pieces. 24 This is just -- this is a</p>	<p>1 filing process. And they don't even look 2 at it unless something invokes them to 3 have a problem.</p> <p>4 So I think in a reference 5 to, you know, the meeting minutes you had 6 from Abrams, tongue-in-cheek, other 7 companies will complain about -- this is 8 very common now -- there's actually whole 9 groups within drug companies that look at 10 competitor's promotion and send complaint 11 documents about what they're doing.</p> <p>12 So, like, the reference that 13 you read to me from Abrams, he says, 14 well, we get complaints. Well, it could 15 also be that. I mean, there's -- the big 16 pharma all have these -- you know, 17 they're kind of review people for other 18 people's promotion.</p> <p>19 So that's -- that's regular 20 pieces.</p> <p>21 Under Subpart H, you 22 cannot -- as I said before, they 23 approximate -- they tell you to 24 approximate, like, 30 to 45 days. And</p>
<p>1 reflection of the review process 2 of promotional pieces, in general, 3 for pre-clearance.</p> <p>4 And it's only under Subpart 5 H do you get this. When you're 6 not under Subpart H, you kind 7 of -- you just get it out there, 8 and then when's you get an NOV or 9 warning letter.</p> <p>10 But this is the normal kind 11 of comments that you get back. 12 And I've had other Subpart H 13 products, and they sound just like 14 this.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. For non-Subpart H products, 17 my understanding, in the pharmaceutical 18 regulatory world, that you have to submit 19 your promotional pieces to the FDA, 20 there's just a 30-day period for the FDA 21 to comment or reject it, right?</p> <p>22 A. So it's actually -- no, 23 that's not the case. 24 So for non-Subpart H, it's a</p>	<p>1 it's not under a PDUFA time frame, so 2 you're kind of at the mercy of them of 3 when you can get your responses back.</p> <p>4 So for every single piece 5 that has ever been produced, for both 6 Fentora and Actiq, we have documents that 7 look just like this. And that was my -- 8 you know, not to belabor, but that was my 9 frustration with the agency and why I 10 asked for that meeting.</p> <p>11 Because -- so you'll get 12 this and they all say, just the way you 13 pointed out that, okay, future ones have 14 to do this. So we go ahead and pull back 15 and change everything because of this.</p> <p>16 And then we'll get the next 17 one that will say not to do that, with 18 future pieces to do that. And that's 19 what my concern with the agency was that, 20 and that's why I said, can we 21 prospectively have a quarterly meeting? 22 So we don't have to keep doing this. And 23 they said no, we can't do that.</p> <p>24 So I wanted to be more</p>
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<p style="text-align: center;">Page 406</p> <p>1 proactive with the agency and make sure 2 that, you know, I thought, suppose we 3 just had a dialogue as opposed to writing 4 back and forth, we'd have a lot more 5 productive pieces and more in line with 6 their thinking. But they did not have 7 the manpower for that.</p> <p>8 Q. Well, they're trying to 9 communicate in these letters to you what 10 they feel is inappropriate about the 11 piece, right?</p> <p>12 MR. DIAMANTATOS: Objection 13 to form. Calls or for 14 speculation.</p> <p>15 THE WITNESS: Yes, this is a 16 recommendation to change. Yes.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. And then so, for instance, 19 on Exhibit-24, this is the November 24th, 20 2004 letter, they are saying one of your 21 Actiq montage journal ads are -- have 22 misleading presentation of information. 23 They have overstatement of efficacy. 24 Minimization of risk. With regard to the</p>	<p style="text-align: center;">Page 408</p> <p>1 that's FDA-ese, that's how they talk. I 2 mean, every piece says that. 3 And I've had promotion 4 pieces pre-cleared, you know, for other 5 things. And that's kind of the dialogue.</p> <p>6 Q. Don't you think Actiq had a 7 problem with overpromotion and promoting 8 off label? Wasn't that a big problem?</p> <p>9 MR. DIAMANTATOS: Objection 10 to form.</p> <p>11 BY MR. CRAWFORD:</p> <p>12 Q. At least in DDMAC's view?</p> <p>13 MR. DIAMANTATOS: Objection 14 to form. Calls for speculation.</p> <p>15 THE WITNESS: So after they 16 gave us guidance, we would revise 17 the piece accordingly, according 18 to what they said. And we never 19 got an NOV or warning letter 20 after.</p> <p>21 So we would take this 22 information, we revise the piece, 23 we produce the piece. We may have 24 gotten an NOV because of the --</p>
<p style="text-align: center;">Page 407</p> <p>1 Actiq detail aid, it omits important risk 2 information. Overstates efficacy. 3 So they're giving you 4 guidance here, in these letters, about 5 what they feel is appropriate, or, 6 actually, what is inappropriate for these 7 ads, right?</p> <p>8 A. That's --</p> <p>9 MR. DIAMANTATOS: Objection 10 to form.</p> <p>11 Go ahead.</p> <p>12 THE WITNESS: Yes, that's 13 what pre-clearance is all about.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. And so, then again, in 16 Exhibit-25, they're talking about 17 overstatement of efficacy again in your 18 promotional pieces, misleading claims. 19 So they are giving you 20 feedback, aren't they, in these letters?</p> <p>21 A. They are.</p> <p>22 And I'm just saying, this 23 terminology, when you see, overstatement 24 of efficacy, that's -- I want to say</p>	<p style="text-align: center;">Page 409</p> <p>1 maybe, one -- there were like -- 2 it went to, like, 15 companies 3 because it was an electronic 4 issue. And that was -- that was 5 more of an electronic issue.</p> <p>6 So when you did Actiq, it 7 cut off the adverse events. And 8 there were -- and we got, the 9 bucket of 15 other companies, all 10 having the same issue. And it was 11 electronic information.</p> <p>12 But other than that, we 13 never had a single NOV on this.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. All right. I'm going to 16 mark the next exhibit.</p> <p>17 MR. JENSEN: 26. 18 - - - 19 (Whereupon, Teva-Marchione 20 Exhibit-26, 21 TEVA_MDL_A_01583458-460, was 22 marked for identification.) 23 - - - 24 BY MR. CRAWFORD:</p>

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<p style="text-align: right;">Page 410</p> <p>1 Q. We marked here a June 25th, 2 2005 letter from Mr. Rappaport, of the 3 FDA, to your attention. It's 4 TEVA_MDL_A_01583458.</p> <p>5 The document stated it's 6 concerning your new drug application, 7 dated November 22nd, 2004 -- or 8 supplemental new drug application. The 9 supplemental new drug application 10 proposes changes to the risk management 11 program, it states.</p> <p>12 So this -- apparently, you 13 had submitted, for the company, proposed 14 changes to the Actiq risk management 15 plan. And this, their statement here, 16 they say, We have completed our review 17 and find the information presented is 18 inadequate and the supplemental 19 application is not approvable.</p> <p>20 Do you recall receiving this 21 letter?</p> <p>22 A. I actually thought we had 23 one response back, out of all our 24 correspondence. So it kind of was in the</p>	<p style="text-align: right;">Page 412</p> <p>1 the kit. And if not, propose a strategy 2 for improvement. 3 So that was one reason they 4 rejected it, right, or found it not 5 approvable?</p> <p>6 MR. DIAMANTATOS: Objection 7 to form. Calls for speculation.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. Is that right?</p> <p>10 A. As you read it.</p> <p>11 Q. Okay. And then it says, 2, 12 The off-label use of Actiq and the number 13 of accidental pediatric exposures to 14 Actiq have been increasing, yet you 15 propose an expansion of the target 16 prescribers. Explain and justify the 17 proposed change, in wording, regarding 18 prescribers from oncologists and pain 19 specialists to physicians with special 20 training.</p> <p>21 That was another thing they 22 wanted you to go back to explain, right?</p> <p>23 A. That's what it says here.</p> <p>24 Q. And then, 3, You propose a</p>
<p style="text-align: right;">Page 411</p> <p>1 back of my head that we got one letter.</p> <p>2 Q. So they rejected the 3 proposed changes you had made to the 4 RiskMAP and submitted to them as a 5 supplemental application, as you're 6 required to do under the RiskMAP, right?</p> <p>7 A. Correct.</p> <p>8 Q. And so they say, underneath, 9 According to -- they say that, 10 Deficiencies are summarized as follows. 11 Number 1, according to patient surveys, 12 only 25 of patients are now receiving 13 welcome kits. The method of distribution 14 of the kits has changed from the original 15 launch method of receiving them directly 16 from the prescriber to either receiving 17 them from the prescriber or via a 18 toll-free number. At the same time, 19 accidental exposures in children are 20 increasing.</p> <p>21 It is instructing you to, 22 Evaluate whether the current method of 23 distribution of the welcome kit provides 24 an effective means for patients to obtain</p>	<p style="text-align: right;">Page 413</p> <p>1 decrease in the surveillance of off-label 2 use of Actiq, in the face of increasing 3 off-label use by prescribers. Justify 4 the proposal for decreased monitoring of 5 off-label use of Actiq and outline 6 effective intervention to discourage it.</p> <p>7 So they have rejected here, 8 at least for these reasons stated, in 9 your view, the proposed Actiq changes to 10 the RiskMAP, right?</p> <p>11 A. That's what it says here.</p> <p>12 Q. And do you know if, at any 13 time prior to -- do you know if, at any 14 time, whether the FDA approved any 15 changes to the RiskMAP, after this date?</p> <p>16 MR. DIAMANTATOS: Objection 17 to form.</p> <p>18 Go ahead.</p> <p>19 THE WITNESS: I don't 20 remember.</p> <p>21 BY MR. CRAWFORD:</p> <p>22 Q. You don't remember if they 23 did?</p> <p>24 A. Normally, the next step is</p>

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<p style="text-align: right;">Page 414</p> <p>1 that we would then send a response. I 2 don't remember what happened. 3 And it was near the -- it 4 was near the launch of Fentora, so I 5 don't know the timing. 6 Q. Okay. Fentora, I think we 7 established, was 2006, right? 8 A. Yes. 9 Q. All right. 10 MR. CRAWFORD: Let's mark 11 the next exhibit. This will be 12 99. And let's mark 533, and we'll 13 just give them both. 14 - - - 15 (Whereupon, Teva-Marchione 16 Exhibit-27, U.S. Department of 17 Justice - Pharmaceutical Company 18 Cephalon to Pay \$425 Million For 19 Off-Label Drug Marketing, was 20 marked for identification.) 21 - - - 22 (Whereupon, Teva-Marchione 23 Exhibit-28, Government's 24 Memorandum for Entry of Plea and</p>	<p style="text-align: right;">Page 416</p> <p>1 A. I mean, I remember the CIA 2 and -- and there was a lawsuit. I kept 3 thinking it was predominantly Provigil. 4 Q. It says here, The United 5 States Attorney General Michael B. 6 Mukasey and Acting United States Attorney 7 Lori Magid today announced the filing of 8 a criminal information against, and a 9 civil settlement with, the pharmaceutical 10 company Cephalon, headquartered in West 11 Chester, PA, for the off-label marketing 12 of three of its drugs. Magid, in today's 13 announcement, were joined by FDA Special 14 Agent-in-Charge Kim Rice -- and others 15 here that they list in the press release. 16 And it says, in the next 17 paragraph, The information alleges that 18 from approximately January 2001 through 19 at least 2006, Cephalon promoted the 20 drugs Actiq, Gabitril and Provigil for 21 uses other than what the federal Food and 22 Drug Administration approved. The 23 company is charged with one count of 24 distribution of misbranded drugs,</p>
<p style="text-align: right;">Page 415</p> <p>1 Sentencing, was marked for 2 identification.) 3 - - - 4 MR. JENSEN: 27 and 28. 5 BY MR. CRAWFORD: 6 Q. Okay. We marked -- 7 MR. CRAWFORD: I'll wait for 8 the witness to get it here. 9 BY MR. CRAWFORD: 10 Q. All right. We marked here a 11 U.S. Department of Justice, Eastern 12 District of Pennsylvania, press release, 13 dated September 29th, 2008. 14 And then -- which is 15 Exhibit-27. And it's entitled, 16 Pharmaceutical Company Cephalon to Pay 17 \$425 Million for Off-Label Drug 18 Marketing. 19 It states here -- first of 20 all, let me ask you, do you have any 21 recollection, during this time period, of 22 Cephalon paying -- being held to pay \$425 23 million for off-label drug marketing 24 during this time period?</p>	<p style="text-align: right;">Page 417</p> <p>1 inadequate directions of use, a 2 misdemeanor offense. 3 Do you, looking at that, 4 recall now that this applied to Actiq? 5 A. Well, it says it here, so. 6 Q. At the time, you did not 7 know it was, up until today? 8 A. You know, I really don't 9 remember. I really don't remember. 10 Q. So was there any discussion 11 in the company about paying this fine and 12 trying to -- 13 A. So we were -- 14 Q. -- do something about this? 15 MR. DIAMANTATOS: Objection 16 to form. And objection to 17 privilege, to the extent it 18 includes conversations with 19 in-house counsel about this 20 particular lawsuit. 21 I just want to clarify that 22 your question isn't calling for 23 those types of communications. 24 BY MR. CRAWFORD:</p>

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<p style="text-align: right;">Page 418</p> <p>1 Q. Do you recall discussing 2 this within the company, this criminal 3 plea and fine?</p> <p>4 A. I never saw this particular 5 document. I understand, you know, the 6 CIA, we signed a review of that and, you 7 know, whatever -- I could not remember if 8 Actiq was in there.</p> <p>9 Reviewing this now, it talks 10 about -- and I've reviewed every single 11 promotion piece, and I know for a fact 12 that none of our pieces ever said 13 anything about migraines, sickle cell, et 14 cetera.</p> <p>15 So I can only assume that 16 the sales rep probably verbally was doing 17 this. All I can answer is for what 18 promotion pieces we had.</p> <p>19 So this has got to be -- you 20 know, it's probably some aberrant sales 21 reps, is the only thing I can assume. 22 But I know the pieces that I pre-cleared 23 with the FDA, and I approved, did not 24 reflect any of these indications or</p>	<p style="text-align: right;">Page 420</p> <p>1 BY MR. CRAWFORD: 2 Q. Or do you know it was just 3 aberrant sales?</p> <p>4 MR. DIAMANTATOS: Let me 5 finish my objection, counsel, 6 please.</p> <p>7 Objection. Form. 8 Mischaracterizes the witness's 9 testimony.</p> <p>10 THE WITNESS: So I'm saying, 11 all the written documents that 12 they gave in a promotion that were 13 supported by the company were all 14 pre-cleared with FDA, submitted to 15 the FDA, reviewed by the promotion 16 review committee, and none of 17 those pieces discussed these 18 off-label uses, nor anything about 19 patients who were opioid 20 nontolerant.</p> <p>21 So the pieces -- all I can 22 address is, I trained the sales 23 force. I told them what they had 24 to do. I got the pieces cleared.</p>
<p style="text-align: right;">Page 419</p> <p>1 non -- or patients who were not yet 2 opioid tolerant.</p> <p>3 So it probably, I'm 4 deducing, it related to, you know, maybe 5 sales activities, that way.</p> <p>6 Q. What about some of the 7 concerns raised by DDMAC?</p> <p>8 I mean, you weren't aware of 9 how they targeted physicians, were you?</p> <p>10 MR. DIAMANTATOS: Objection 11 to form. Foundation. Assumes 12 facts.</p> <p>13 THE WITNESS: I didn't know 14 the details of how they chose 15 which categories were targeted, if 16 that answers your question.</p> <p>17 BY MR. CRAWFORD:</p> <p>18 Q. So, I mean, you're 19 speculating that it was just some 20 aberrant sales reps that caused this fine 21 to be imposed and guilty plea, right?</p> <p>22 MR. DIAMANTATOS: Objection. 23 Form. Mischaracterizes the 24 testimony.</p>	<p style="text-align: right;">Page 421</p> <p>1 What they did with that, you know, 2 I didn't control that.</p> <p>3 So I don't -- I don't 4 know -- you know, it's kind of 5 like going back to the details of 6 what these reasons were. I don't 7 know the specifics. All I can 8 talk to are the pieces, the 9 promotion pieces, that we had 10 pre-cleared and sent to the FDA. 11 And none of them, none of them 12 talked about off-label use or 13 nontolerant/opioid tolerant.</p> <p>14 BY MR. CRAWFORD: 15 Q. But there are other aspects 16 of sales and marketing. There's 17 targeting of doctors. There's, you know, 18 how they're trained.</p> <p>19 And that wasn't your job to 20 train the sales reps, was it?</p> <p>21 A. Yes, I trained the sales 22 reps on the RiskMAP program. Yes.</p> <p>23 So I can't -- that's the 24 only thing that I can tell you that I'm</p>

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<p>1 responsible for. What happened outside 2 of that, you know, what was -- what they 3 were told to do outside of my area, I 4 can't answer to.</p> <p>5 Q. Right. Well, just -- we've 6 marked Exhibit-28, which is the 7 Government's Memorandum For Entry of Plea 8 and Sentencing.</p> <p>9 If you can just turn to Page 10 3, it does list the reasons here, or the 11 off-label practices, and its training of 12 its sales staff that the government 13 believed ignored legal restrictions on 14 promoting these drugs.</p> <p>15 Do you see that on Page 3?</p> <p>16 A. I do.</p> <p>17 Q. Okay. And the first one is, 18 Cephalon had its sales representatives 19 call on doctors who would not normally 20 prescribe the defendant's drugs in the 21 course of the doctor's practice.</p> <p>22 That doesn't have anything 23 to do with the promotional pieces, does 24 it?</p>	<p>1 Go ahead. 2 THE WITNESS: Yes. I was 3 only -- I was only training for, 4 like, an hour or an hour 5 and-a-half. I don't know how 6 long -- so they probably had a 7 couple of days. So I don't know 8 where that came from.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. It says, Cephalon's 11 compensation and bonus structure 12 encouraged off-label marketing.</p> <p>13 That's not anything to do 14 with regulatory or you, right?</p> <p>15 A. Nothing.</p> <p>16 Q. And then, et cetera, et 17 cetera. I won't keep going into that.</p> <p>18 A. Right.</p> <p>19 Q. So -- all right.</p> <p>20 MR. CRAWFORD: We'll mark 21 the next exhibit.</p> <p>22 MR. JENSEN: 29.</p> <p>23 - - -</p> <p>24 (Whereupon, Teva-Marchione</p>
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<p>1 MR. DIAMANTATOS: Objection 2 to form. Foundation. Calls for 3 speculation.</p> <p>4 THE WITNESS: No. I think 5 it goes back to the targeting 6 issue, and that was not under my 7 purview.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. And then they say, Cephalon 10 trained its sales representatives on 11 techniques to prompt the doctors into 12 off-label conversations.</p> <p>13 That was another claim by 14 the government, right?</p> <p>15 A. That's what it says here.</p> <p>16 But all I did was train them 17 on the RiskMAP and the concerns of the 18 FDA. So that's the only thing I can 19 really speak to.</p> <p>20 Q. So do you think that sales 21 reps received other training, maybe, that 22 you didn't attend?</p> <p>23 MR. DIAMANTATOS: Objection 24 to form.</p>	<p>1 Exhibit-29, TEVA_CHI_00028341-691, 2 was marked for identification.)</p> <p>3 - - -</p> <p>4 MR. CRAWFORD: We're going 5 to mark four exhibits here just so 6 we can kind of knock them out all 7 at once.</p> <p>8 - - -</p> <p>9 (Whereupon, Teva-Marchione 10 Exhibit-30, 11 TEVA_MDL_A_08399245-251, was 12 marked for identification.)</p> <p>13 - - -</p> <p>14 (Whereupon, Teva-Marchione 15 Exhibit-31, 16 TEVA_MDL_A_08399245-251, was 17 marked for identification.)</p> <p>18 - - -</p> <p>19 (Whereupon, Teva-Marchione 20 Exhibit-32, 21 TEVA_MDL_A_02074924-969, was 22 marked for identification.)</p> <p>23 - - -</p> <p>24 BY MR. CRAWFORD:</p>

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<p style="text-align: center;">Page 426</p> <p>1 Q. So at some point in -- if 2 you take a look at what we marked here as 3 Exhibits-29, 30, 31 and 32, 29 is a 4 September 19th, 2006 letter from you to 5 Dr. Rappaport, of the FDA, referencing 6 the new drug application -- 7 A. If I can correct you, it 8 wasn't a letter from me. It was from 9 Penny Levin. 10 Q. Very good. So she worked in 11 your department, right? 12 A. Right. And that's what I 13 was trying to remember. I was looking 14 for my org chart, because I think that 15 may have been the time I went to 16 oncology. I can't remember. I mean, 17 there was an overlap. 18 Q. Let's take a look at 19 Exhibit-1. I want to get clear, because 20 I think you were here in '07 to 2011, you 21 went to oncology in '11. 22 So if you can check 23 Exhibit-1 -- 24 A. Yeah, maybe. I just want to</p>	<p style="text-align: center;">Page 428</p> <p>1 you were overseeing that effort, right? 2 A. It pretty much went over to 3 Penny from that point on. 4 Q. Let's go, actually, to your 5 first bullet point in the resume. 6 Actually -- yeah, your first 7 bullet point under, Accomplishments. 8 A. Right. 9 Q. And you say, Successfully 10 negotiated multiple product approvals. 11 And Fentora is on that list, 12 right? 13 A. That's correct. This is 14 a -- I mean, this is a supplement. 15 So I'm saying, after we got 16 promoted, there was a transition. 17 Q. Right. But this is not a 18 supplement. 19 This is an NDA for Fentora, 20 right? It says, New drug application. 21 A. This supplement contains -- 22 with regard to the Fentora RiskMAP. 23 Q. And this is one of your 24 accomplishments, was to get this</p>
<p style="text-align: center;">Page 427</p> <p>1 double check. 2 Q. And make sure that you were 3 here as senior director -- or as senior 4 director and group leader, regulatory 5 affairs -- 6 A. Okay. 7 Q. -- from 2007 to 2011. 8 Is that right? Do you agree 9 with that? 10 A. Yes. I think right around 11 the time I got the approval for Fentora, 12 we kind of switched. There was -- 13 Q. Take a look at your -- 14 A. I do understand the title. 15 But that doesn't necessarily 16 mean that I wasn't working on pain at 17 the time. So it's a little -- I don't 18 know exactly. 19 So all I'm saying is, when I 20 was group leader, I may not have been -- 21 they may have switched over yet. That's 22 what I was trying to figure out. 23 I can still talk to this. 24 Q. When Fentora was approved,</p>	<p style="text-align: center;">Page 429</p> <p>1 approved, right? 2 A. An amendment -- so it's an 3 amendment to the NDA. Okay. I was just 4 trying to ascertain. 5 So this was -- the amendment 6 wasn't yet approved. So, yes, I was 7 working on this at the time. 8 Q. So this is -- this is 9 getting the approval of Fentora here in 10 September of '06, you're working towards, 11 right? 12 A. That is correct. 13 Q. And that was one of your 14 accomplishments you outlined in your 15 resume, right? 16 A. That's correct. 17 Q. So you were, in fact, as 18 head of that regulatory department, 19 overseeing this approval process, right? 20 A. Yes, I was. 21 Q. So -- and then we have here, 22 they reference -- you state here in this 23 letter, it's TEVA_CHI 00028341, 24 Exhibit-29, you say, in your September</p>

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<p>1 19th letter -- or, actually, Ms. Levin 2 does, 2006 letter, Reference is also 3 made -- this is the last part of 4 Paragraph 1.</p> <p>5 Reference is also made to 6 telephone conference request from Ms. Kim 7 Compton, FDA project manager, on 8 September 18th, 2006, who requested that 9 a final submission of the revised Fentora 10 RiskMAP, along with attachments, be 11 submitted as an amendment to the NDA to 12 reflect all changes agreed upon during 13 the above-referenced FDA communications.</p> <p>14 So this attachment here, 15 this attaches the FDA -- or the RiskMAP, 16 right?</p> <p>17 A. It appears that way, yes.</p> <p>18 Q. And the RiskMAP starts at 19 Page, if I'm correct, 28345, right?</p> <p>20 A. Yes.</p> <p>21 Q. And it also references, in 22 the September 19th letter, Reference -- 23 this is the second sentence, Reference is 24 also made to the discipline review</p>		<p>1 labeling. And the other part, RiskMAP. 2 And the RiskMAP, at that time, was 3 considered labeling.</p> <p>4 Q. So they're making -- they're 5 telling you what you needed to change in 6 the Fentora RiskMAP, right --</p> <p>7 MR. DIAMANTATOS: Objection.</p> <p>8 BY MR. CRAWFORD:</p> <p>9 Q. -- before it could be 10 approved --</p> <p>11 MR. DIAMANTATOS: Objection.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. -- in these letters?</p> <p>14 MR. DIAMANTATOS: Objection 15 to form. Vague.</p> <p>16 And are you referring to all 17 three exhibits? If you can just 18 be clear so she can --</p> <p>19 MR. CRAWFORD: 30 and 31.</p> <p>20 Very good. Thank you, counsel.</p> <p>21 THE WITNESS: So 31 is here. 22 So everything was considered 23 draft, when you submit it under 24 the NDA.</p>
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<p>1 letters, August 29th and September 7th. 2 So I have attached those 3 discipline review letters as Exhibits-30 4 and 31.</p> <p>5 Do you see those?</p> <p>6 A. 30 and 31. Yes, I do.</p> <p>7 Q. And those, in fact, are 8 addressed to you, right?</p> <p>9 A. They are.</p> <p>10 Q. They're from the FDA. 11 And can you explain what 12 these discipline review letters are?</p> <p>13 A. I'd have to -- you know, I 14 just got them.</p> <p>15 But just in general, 16 discipline review letter is FDA feedback 17 for a -- you have to read it.</p> <p>18 So it's the RiskMAPs 19 associated with -- complete response -- 20 oh, so this is associated with -- so a 21 review -- a review letter is just 22 comments back, it could be on any part of 23 your NDA.</p> <p>24 So this is obviously on our</p>	<p>1 So these are comments to 2 change -- the comments to the 3 RiskMAP that they want changed 4 prior to they approved the FDA -- 5 I mean, approve the NDA.</p> <p>6 And, likewise, the changes 7 to the package insert for Number 8 31.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. All right. And so in 11 Exhibit-29, Ms. Levin is referencing 12 these discipline review letters and 13 indicating that the Fentora RiskMAP has 14 changed, final submission to reflect the 15 changes agreed upon, right?</p> <p>16 A. Formal response -- so this 17 constitutes Cephalon's response to the 18 agency's requests. That's what it says 19 here.</p> <p>20 Q. So 32, then, was the 21 approval letter for the Fentora NDA, 22 right?</p> <p>23 And that's addressed to you?</p> <p>24 A. It was. Yep. Yes, it is.</p>	

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<p style="text-align: right;">Page 434</p> <p>1 Q. So if you look at the fourth 2 paragraph down, it says, This new drug 3 application -- actually, before that. 4 Let's go through this. So 5 the fourth paragraph down, it says, This 6 new drug application provides for the use 7 of Fentora for the management of 8 breakthrough pain in patients with cancer 9 who are already receiving and who are 10 tolerant to opioid therapy for their 11 underlying persistent cancer pain. 12 So that's the same 13 indication as Actiq, correct? 14 A. That's correct. 15 Q. So only -- Fentora, like 16 Actiq, could only be -- was only 17 indicated for use in cancer patients, 18 right?</p> <p>19 MR. DIAMANTATOS: Objection 20 to form.</p> <p>21 Go ahead.</p> <p>22 THE WITNESS: That's 23 correct.</p> <p>24 BY MR. CRAWFORD:</p>	<p style="text-align: right;">Page 436</p> <p>1 prescribers, pharmacies, nurses and 2 patients about the risks and benefits of 3 Fentora. 4 Right? 5 A. That's what it says, yes. 6 Q. And then 3 -- skipping to 7 3 -- or 2, Implementation of a reporting 8 and data collection system for safety 9 surveillance. 10 And, 3, implementation of a 11 plan to monitor, evaluate, and determine 12 the incidence of use of Fentora by opioid 13 nontolerant individuals, misuse of 14 Fentora and unintended, accidental, 15 exposure to Fentora. 16 So that was, according to 17 the letter, what the FDA viewed as the 18 primary goals of the RiskMAP, right? 19 MR. DIAMANTATOS: Objection 20 to form.</p> <p>21 THE WITNESS: The components 22 of the RiskMAP, yes.</p> <p>23 BY MR. CRAWFORD: 24 Q. So it's saying here that the</p>
<p style="text-align: right;">Page 435</p> <p>1 Q. So the last paragraph, Your 2 Fentora RiskMAP, it says, is an important 3 part of the postmarketing risk management 4 for fentanyl buccal tablet. The primary 5 goals of your RiskMAP are to minimize the 6 use of Fentora by opioid nontolerant 7 individuals, minimize misuse of Fentora 8 and minimize the unintended accidental 9 exposure to Fentora. 10 So you understood the 11 RiskMAP to be an important part of the 12 postmarketing risk management, in the 13 FDA's views, right?</p> <p>14 MR. DIAMANTATOS: Objection 15 to form. Speculation. 16 Go ahead.</p> <p>17 THE WITNESS: Obviously, 18 from the text it is an important 19 part.</p> <p>20 BY MR. CRAWFORD: 21 Q. Then it says, Your RiskMAP 22 must include the following components. 23 Implementation of a program and 24 distribution of materials to educate</p>	<p style="text-align: right;">Page 437</p> <p>1 Fentora RiskMAP, submitted on August 2 31st, 2005, and finalized in your 3 submission dated September 19th, 2006, 4 and as described in the attached 5 document, adequately addresses each of 6 these requirements. 7 So they are referring to 8 Exhibit-29 here, right, the RiskMAP 9 attached to that? Is that your 10 understanding of the letter? 11 MR. DIAMANTATOS: Objection 12 to form. Calls for speculation. 13 BY MR. CRAWFORD: 14 Q. I'm trying to establish that 15 that's the RiskMAP they approved, right? 16 A. I'm still -- submitted 17 August 31 -- I'm just trying to find 18 that. 19 Q. It says, Finalized in your 20 submission dated September 19th, 2006 and 21 as described in the attached document. 22 A. So it's 8/29, is that the 23 date? 24 Q. It's September 19th, 2006.</p>

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<p style="text-align: right;">Page 438</p> <p>1 A. September 19th. I'm just 2 trying to find that submission. 3 Q. That would be Exhibit-29. 4 A. 29? 5 Q. Yes. 6 A. Got you. 7 Q. And it's Page 28345. 8 A. Okay. 9 Q. What I'm trying to do is 10 establish that the one you sent to them, 11 or Ms. Levin sent to them on September 12 19th, 2006, is the one that they're 13 referencing here in the approval letter 14 that that's approved?</p> <p>15 A. I understand. Thank you.</p> <p>16 Q. Is that how you understood 17 the letter?</p> <p>18 A. Yes, that's how I understand 19 it.</p> <p>20 Q. So you understand the final 21 RiskMAP that was approved is actually the 22 one that is actually attached to 23 Exhibit-29?</p> <p>24 A. That's my -- yes.</p>	<p style="text-align: right;">Page 440</p> <p>1 Q. And was somebody at 2 regulatory in charge, again, of ensuring 3 that reports were made to the FDA about 4 the RiskMAP?</p> <p>5 A. Yes. And in this case, it 6 was Penny.</p> <p>7 Q. Okay. So Penny took over 8 that function from you for this, or did 9 you take any responsibility for it?</p> <p>10 A. I think anything only 11 elevated to me if there was a significant 12 issue or concern.</p> <p>13 Q. But do you remember her 14 elevating anything to you about the 15 RiskMAP reporting for Fentora?</p> <p>16 A. I don't actually remember.</p> <p>17 Q. But she was, really, the 18 primary responsible person for that?</p> <p>19 A. Yes, she was.</p> <p>20 Q. And then the approval letter 21 does attach the label, at Page 928. 22 You'll see a big black box there.</p> <p>23 Is that a black box warning?</p> <p>24 A. Yes, it is.</p>
<p style="text-align: right;">Page 439</p> <p>1 Q. All right. It states, This 2 plan includes ongoing assessment and 3 periodic reporting to FDA of the 4 operation of the program and needed 5 revisions, if any. Any change to the 6 program must be discussed with FDA prior 7 to its institution and is subject to the 8 FDA's determination that the required 9 components are still present. We expect 10 your continued cooperation to resolve any 11 problems regarding the Fentora RiskMAP 12 that may be identified following approval 13 of this application.</p> <p>14 So it was your understanding 15 that, in approving this, that there was 16 an ongoing assessment and periodic 17 reporting to the FDA on the operation of 18 the RiskMAP program, similar to what you 19 were reporting for Actiq, right?</p> <p>20 MR. DIAMANTATOS: Objection 21 to form.</p> <p>22 THE WITNESS: That's my 23 understanding, yes.</p> <p>24 BY MR. CRAWFORD:</p>	<p style="text-align: right;">Page 441</p> <p>1 Q. And can you explain to me 2 what a black box warning is, in 3 regulatory parlance?</p> <p>4 A. So it shows concerns of the 5 product that can affect safety and 6 explains the FDA has revised, not just 7 the concerns, but how you can address 8 those concerns. So if you see a certain 9 adverse event, how you can actually 10 diminish it or treat that adverse event.</p> <p>11 And that's what the box is.</p> <p>12 Q. And they call it black box 13 because it's in a black box, right?</p> <p>14 A. That's correct.</p> <p>15 Q. And it's the most serious 16 type of warning you can give in a package 17 insert or label, is a black box warning, 18 right?</p> <p>19 A. That's correct, yes.</p> <p>20 Q. So it's -- a black box 21 warning is always put right in the front 22 on the first page, right?</p> <p>23 A. Yes, that's correct.</p> <p>24 Q. And here we have a black box</p>

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<p style="text-align: right;">Page 442</p> <p>1 warning for Fentora about it containing 2 fentanyl, an opioid agonist and a 3 Schedule II controlled substance with an 4 abuse liability similar to other opioid 5 analgesics.</p> <p>6 So there are black box 7 warnings here, would you agree, that 8 pertains to abuse of the drug, correct?</p> <p>9 A. Yes.</p> <p>10 Q. And the black box warning, 11 the second paragraph, also contains a 12 bolded warning about the indicated use 13 for management of breakthrough pain in 14 patients with cancer, right, who are 15 already receiving -- who are tolerant to 16 opioid therapy for their underlying 17 persistent cancer pain; that's in the 18 black box, too, right?</p> <p>19 A. Yes, it is.</p> <p>20 Q. Let's go to the next doc. 21 Actually, go to Page -- 22 Exhibit-29. I had a couple of questions 23 about the RiskMAP. 24 So this RiskMAP contains</p>	<p style="text-align: right;">Page 444</p> <p>1 was its appearance of a lollipop, 2 which would be enticing to 3 children, whereas Fentora was a 4 buccal tablet, so it didn't 5 have -- you know, it looked like a 6 pill or lozenge. So they weren't 7 as concerned of the pediatric -- I 8 shouldn't say weren't as 9 concerned, but it wasn't the 10 emphasis as much as it was for 11 Actiq.</p> <p>12 BY MR. CRAWFORD:</p> <p>13 Q. But certainly misuse and 14 abuse were a concern?</p> <p>15 A. Yes, they were.</p> <p>16 Q. So, in fact, if you look at 17 Page 28347, which is about the sixth page 18 in here, that's the first page under, 19 Background.</p> <p>20 A. Yes.</p> <p>21 Q. Do you see that, under the 22 middle there, it says, As Fentora 23 contains a potent opiate, fentanyl, the 24 SECURE program is focused on minimizing</p>
<p style="text-align: right;">Page 443</p> <p>1 similar elements -- do you recall at all 2 reviewing the RiskMAP for Fentora?</p> <p>3 A. We did. It started out 4 similar, based upon what we had for 5 Actiq. It was right around the time the 6 FDA actually was going to be issuing 7 RiskMAP guidance. So they were trying to 8 have consistency with other products.</p> <p>9 And there were a lot of new 10 elements that they took from the device 11 group. A lot of it is, like, 12 prospective -- so it's prospective 13 analysis. And so it started to morph 14 into a very different type of document 15 than the Actiq one.</p> <p>16 Q. All right. But it did 17 contain a lot of elements similar to the 18 Actiq one, right?</p> <p>19 MR. DIAMANTATOS: Objection 20 to form.</p> <p>21 THE WITNESS: I think the 22 most significant difference was, 23 because of the FDA's -- one of the 24 most critical concerns about Actiq</p>	<p style="text-align: right;">Page 445</p> <p>1 the three risks associated with, one, use 2 of Fentora by opioid nontolerant 3 individuals, misuse, abuse and diversion 4 of Fentora and unintended exposure to 5 Fentora.</p> <p>6 That's similar concerns or 7 rationales that were behind the Actiq 8 RiskMAP, right?</p> <p>9 A. Well, the pediatric issue 10 was removed.</p> <p>11 Q. Good point, yes.</p> <p>12 So if you go to the next 13 page, it's Page 4 of the RiskMAP, up at 14 the top, it says 4.</p> <p>15 But if you go to the bottom, 16 it says, In designing this RiskMAP, 17 Cephalon has focused on ensuring the 18 integrity of its supply chain for 19 Fentora; 2, tools that can be used to 20 educate broadly; and, 3, mechanisms by 21 which cases of diversion or abuse can be 22 detected promptly. In this regard, 23 Cephalon will monitor geographical 24 evidence of abuse through the use of the</p>

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<p style="text-align: center;">Page 446</p> <p>1 RADARS system, see below, to assure that 2 rapid interventions can be applied to 3 areas where there may be a signal of 4 increasing abuse potential. 5 So the hope was here that 6 the RiskMAP would allow Cephalon to 7 identify -- that they would educate, 8 using these tools, educate broadly, but 9 also to identify problems and focus in on 10 solving them, right?</p> <p>11 MR. DIAMANTATOS: Objection 12 to form. Foundation. Calls for 13 speculation.</p> <p>14 BY MR. CRAWFORD:</p> <p>15 Q. Is that a good summary of 16 what the FDA wanted?</p> <p>17 MR. DIAMANTATOS: Objection 18 to form. Foundation. Calls for 19 speculation.</p> <p>20 THE WITNESS: One of the 21 biggest issues in reference to the 22 SECURE program was to try to have 23 a closed-loop system where, if 24 something was going to be diverted</p>	<p style="text-align: center;">Page 448</p> <p>1 incidents of abuse or diversion. 2 You understand this was one 3 of the responsibilities of the company 4 here in preventing abuse and misuse that 5 the RiskMAP imposed, right?</p> <p>6 MR. DIAMANTATOS: Objection 7 to form.</p> <p>8 THE WITNESS: That's my 9 understanding.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. And then on Page 11, there 12 is, 3, The overall strategy for 13 prescribing, dispensing, using Fentora. 14 And 3.1 is, Physician education.</p> <p>15 So they're saying here, 16 basically -- I don't want -- I am not 17 going to read it all, but they're 18 basically outlining steps that the 19 company was to take with regard to 20 education of physicians about the drug, 21 right?</p> <p>22 MR. DIAMANTATOS: Objection 23 to form.</p> <p>24 THE WITNESS: Right.</p>
<p style="text-align: center;">Page 447</p> <p>1 from any point from the 2 manufacturer to the patient, that 3 there was a more controlled 4 tracking of that.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. And if you turn to Page 9, 7 it lists the RiskMAP goals and 8 objectives.</p> <p>9 And under 2.1, one of the 10 goals was abuse, misuse and diversion of 11 Fentora should not occur; is that right?</p> <p>12 A. That's correct.</p> <p>13 Q. And then Goal 2 is 14 elaborated upon in 2.2. In Roman 15 Numeral III, it says, Reduce the 16 potential abuse, misuse and diversion of 17 Fentora by, A, providing education to 18 healthcare personnel and to pertinent 19 nationwide demographic communities; B, 20 performing ongoing surveillance of and 21 reaction to geographical outbreaks of 22 abuse, misuse and diversion; and, C, 23 cooperating with and providing assistance 24 to law enforcement in investigations of</p>	<p style="text-align: center;">Page 449</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. And then going to Page 15, 3 down at the bottom, 3.6.1, Strategy and 4 tools associated with Goal 1, Fentora 5 should be used only by opioid-tolerant 6 patients with cancer.</p> <p>7 It does state, A variety of 8 tools will be used to communicate and 9 reinforce the message that Fentora should 10 only -- should be used only by 11 opioid-tolerant patients with cancer.</p> <p>12 So that was -- the RiskMAP 13 contains, then, a list of tools that were 14 available to Cephalon to make sure that 15 only cancer patients use the drug, right?</p> <p>16 A. That's my understanding.</p> <p>17 Q. Okay. And then at Page 16, 18 the first full paragraph there, it says, 19 From the outset, healthcare professionals 20 will be alerted to the risks of this new 21 product through product labeling and 22 promotion. They will be educated about 23 the product's approved indication, as 24 well as about the definition of opioid</p>

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<p>1 tolerant as described in the package 2 insert.</p> <p>3 Tools directed -- moving 4 down, Tools directed towards prescribers 5 will include introductory letters, visits 6 and assessments by Cephalon field 7 representatives, Fentora website and 8 targeted education and outreach programs 9 directed to pain centers of excellence 10 and professional societies.</p> <p>11 So these were tools that the 12 FDA expected Cephalon to use proactively 13 to educate doctors about the proper use 14 of the drug, right?</p> <p>15 MR. DIAMANTATOS: Objection 16 to form. Foundation.</p> <p>17 Speculation.</p> <p>18 Go ahead and answer.</p> <p>19 THE WITNESS: Just to be 20 clear, we proposed this to the 21 FDA. So we voluntarily are 22 saying, we're going to be doing 23 this, and the FDA agreed.</p> <p>24 So it wasn't that the FDA</p>	<p>1 right? 2 A. And that's correct. It's 3 written in terms of the loop, you know, 4 so the points of intervention. So every 5 place that anything touched hands, how 6 they would communicate the proper 7 information.</p> <p>8 Q. And so on Page 28, some of 9 these tools, looking down, the third one 10 down, Take a look at that, starting with, 11 Launch professional societies.</p> <p>12 A. Right.</p> <p>13 Q. So professional societies, 14 at launch, will be contacted to offer 15 educational opportunities to learn about 16 Fentora and key messages and risks 17 described in the RiskMAP, including the 18 risk of misuse, abuse and diversion.</p> <p>19 That was one tool that was 20 being offered, right?</p> <p>21 A. More than offered. It's 22 more --</p> <p>23 Q. Implemented?</p> <p>24 A. Implemented, yes.</p>
<p>1 said, you do this and we agreed. 2 We prompted this.</p> <p>3 BY MR. CRAWFORD:</p> <p>4 Q. Very good point.</p> <p>5 So you -- the company was 6 involved in drafting this up, and the FDA 7 provided comment back?</p> <p>8 A. Exactly.</p> <p>9 Q. And so this was the final 10 one approved.</p> <p>11 But, you're right, the 12 company was the one that said, this is 13 what we'll do to make sure the drug is 14 safely and properly used?</p> <p>15 A. That's correct, yes.</p> <p>16 Q. Thank you.</p> <p>17 So if you could go to Page 18 26, you have a table there. It's a Goal 19 2 summary table, Goal 2 being misuse, 20 abuse and diversion of Fentora.</p> <p>21 These charts here outline 22 the various tools that Cephalon intended 23 to use to ensure that there was no 24 misuse, abuse, or diversion of Fentora,</p>	<p>1 Q. And then going to 29, you 2 have several ongoing tools.</p> <p>3 One -- the top one being, 4 Cephalon will implement medical education 5 directed to geographic hotspots to focus 6 on preventing and/or minimizing misuse, 7 abuse and diversion of prescription 8 drugs.</p> <p>9 Below that, Launch an 10 ongoing -- two below, Cephalon will 11 support independent education on 12 prescription drug misuse, abuse and 13 diversion targeted to physicians likely 14 to prescribe Fentora.</p> <p>15 So I didn't read them all, 16 but these were tools that the -- that 17 Cephalon had agreed to utilize to prevent 18 misuse and abuse, and the FDA agreed with 19 this plan and approved Fentora, 20 conditioned upon Cephalon executing this 21 plan, correct?</p> <p>22 MR. DIAMANTATOS: Objection 23 to form.</p> <p>24 THE WITNESS: That's my --</p>
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<p>1 yes, that's my understanding.</p> <p>2 BY MR. CRAWFORD:</p> <p>3 Q. Go to Page 54. I just want</p> <p>4 to point out one more tool here.</p> <p>5 The second one down, Number</p> <p>6 6, Page 54, at the top. Second one down,</p> <p>7 Number 6.</p> <p>8 So that one is a -- the tool</p> <p>9 is, Direct risk communication by Cephalon</p> <p>10 field representatives.</p> <p>11 So one of them was, At</p> <p>12 launch and ongoing, prescribers will be</p> <p>13 informed, in person, of the key messages</p> <p>14 and elements of the Fentora RiskMAP,</p> <p>15 including the potentially</p> <p>16 life-threatening risk of use by an opioid</p> <p>17 nontolerant individual, the high</p> <p>18 potential for Fentora abuse, as well as</p> <p>19 the risk of misuse and diversion and the</p> <p>20 potentially life-threatening risk of</p> <p>21 accidental use of Fentora in children or</p> <p>22 adults.</p> <p>23 That was, again, a tool that</p> <p>24 Cephalon intended to use with its sales</p>	<p>1 sales force, that would be a tool that</p> <p>2 the marketing and sales department were</p> <p>3 required to ensure were utilized, right?</p> <p>4 A. I'd have to check. It could</p> <p>5 be -- it could be medical affairs, too,</p> <p>6 the MSLs. So it could have been -- it</p> <p>7 could have been that group also.</p> <p>8 Q. Right. But it could also be</p> <p>9 sales and marketing, if they're sending</p> <p>10 out sales reps, right?</p> <p>11 A. That's true. But does it</p> <p>12 say sales reps? I didn't know if it said</p> <p>13 that specifically.</p> <p>14 Q. Yes, it did -- the last one</p> <p>15 we read was direct risk communication by</p> <p>16 Cephalon field representatives, which is</p> <p>17 a sales representative, right?</p> <p>18 A. I'm not quite sure. It</p> <p>19 could have been MSLs. I don't know how</p> <p>20 they define that, at that point.</p> <p>21 Q. Okay. Well, 10 is, Launch</p> <p>22 an ongoing -- Cephalon will contact each</p> <p>23 of the identified top 25 pain centers of</p> <p>24 excellence to offer further educational</p>
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<p>1 force, right?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. Moving down to 10, on</p> <p>4 the next page, again, Physician education</p> <p>5 directed at pain centers of excellence.</p> <p>6 What is a pain center of</p> <p>7 excellence? Do you know what that is?</p> <p>8 A. No, I don't. Sorry.</p> <p>9 Q. Were these tools that the</p> <p>10 marketing department were supposed to</p> <p>11 make sure were implemented?</p> <p>12 MR. DIAMANTATOS: Objection.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Marketing and sales, rather?</p> <p>15 MR. DIAMANTATOS: Objection</p> <p>16 to form. Foundation.</p> <p>17 THE WITNESS: So they</p> <p>18 were -- so, I'm sorry, can you</p> <p>19 repeat that question?</p> <p>20 BY MR. CRAWFORD:</p> <p>21 Q. Yeah.</p> <p>22 I'm just wondering, these</p> <p>23 were tools -- if they deal with the sales</p> <p>24 force and physician education through the</p>	<p>1 opportunities to learn about Fentora,</p> <p>2 including the three principle risks</p> <p>3 identified in the RiskMAP. Specific</p> <p>4 risks of use by opioid nontolerant</p> <p>5 individuals, the risk of misuse, abuse,</p> <p>6 and diversion, and the risk of accidental</p> <p>7 exposure to Fentora will be addressed.</p> <p>8 So the pain centers are</p> <p>9 supposed to be contacted, under this</p> <p>10 plan, to educate -- to offer educational</p> <p>11 opportunities to learn about Fentora,</p> <p>12 correct?</p> <p>13 A. It appears that way, yes.</p> <p>14 MR. CRAWFORD: So moving on</p> <p>15 to Document 661.</p> <p>16 - - -</p> <p>17 (Whereupon, Teva-Marchione</p> <p>18 Exhibit-33,</p> <p>19 TEVA_MDL_A_00038282-295, was</p> <p>20 marked for identification.)</p> <p>21 - - -</p> <p>22 MR. JENSEN: Exhibit-33.</p> <p>23 BY MR. JENSEN:</p> <p>24 Q. We've marked Exhibit-33,</p>

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<p style="text-align: right;">Page 458</p> <p>1 which is a -- let me ask you this, do you 2 recall, at any point in time, trying to 3 seek an expanded indication for Fentora 4 for noncancer uses?</p> <p>5 A. Vaguely.</p> <p>6 Q. And were you involved in 7 that effort?</p> <p>8 A. Well, I was at this meeting, 9 so I probably was.</p> <p>10 Q. Okay. All right. So this 11 is a letter from the FDA to you at 12 Cephalon, dated July 17th, 2007. 13 So what do you recall 14 about -- and it includes minutes from a 15 meeting here. The meeting minutes, the 16 meeting objective -- like you pointed 17 out, you attended this meeting, correct?</p> <p>18 A. Yes.</p> <p>19 Q. Right. And who is Eric 20 Floyd?</p> <p>21 A. That was my manager at the 22 time.</p> <p>23 Q. All right. And Penny Levin 24 as well, she worked in your department?</p>	<p style="text-align: right;">Page 460</p> <p>1 persistent pain.</p> <p>2 Q. And do you recall what the 3 FDA's response was in this meeting?</p> <p>4 A. No, I'd have to review it.</p> <p>5 Sorry.</p> <p>6 Q. Maybe -- okay.</p> <p>7 They had a bunch of 8 responses here before they could approve 9 it.</p> <p>10 They were trying to give 11 you -- were they trying to give you some 12 kind of guidance on getting it approved?</p> <p>13 MR. DIAMANTATOS: Objection 14 to form.</p> <p>15 THE WITNESS: That's -- 16 that's what the meeting -- the 17 intention of the meeting, yes.</p> <p>18 BY MR. CRAWFORD:</p> <p>19 Q. I think I want to direct 20 your attention in particular to Page 6 of 21 the letter, at the bottom, Question 11. 22 These are questions posed by 23 the company to the FDA prior to the 24 meeting, right?</p>
<p style="text-align: right;">Page 459</p> <p>1 A. Right. She reported to me.</p> <p>2 Q. All right. And, again, Mr. 3 Rappaport at the FDA attended the 4 meeting, correct?</p> <p>5 A. Yep.</p> <p>6 Q. And the meeting objective is 7 stated below. And it is -- it states 8 that the purpose of the meeting was to 9 provide the sponsor with feedback on the 10 questions in their May 11, 2007 meeting 11 package, which were specifically related 12 to the submission of a supplemental new 13 drug application to expand the indication 14 for their product.</p> <p>15 So what was -- what was 16 Cephalon trying to do here?</p> <p>17 A. I'm deducing they were 18 trying to have the product approved for a 19 broader indication than for just cancer.</p> <p>20 Q. And what was the broader 21 indication they were seeking?</p> <p>22 A. For any -- for anybody who 23 has breakthrough pain and who is tolerant 24 to opioid therapy, for their underlying</p>	<p style="text-align: right;">Page 461</p> <p>1 A. That's correct.</p> <p>2 Q. And this question was, Does 3 the agency concur that the currently 4 approved RiskMAP for Fentora is 5 acceptable to support the use of Fentora 6 in opioid-tolerant patients with 7 persistent pain?</p> <p>8 That means with -- broadly, 9 anyone with persistent pain, whether 10 Fentora should be approved, right?</p> <p>11 A. That's my understanding.</p> <p>12 Q. And so the FDA response is 13 here. And the FDA -- what, generally, 14 was their response to this question?</p> <p>15 MR. DIAMANTATOS: Objection 16 to form.</p> <p>17 THE WITNESS: Do you want me 18 to read it to you?</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. Well, you were at this 21 meeting. And you can either read it -- 22 you're welcome to read it or give your 23 recollection of what they thought about 24 the RiskMAP.</p>

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<p style="text-align: right;">Page 462</p> <p>1 A. I just have to review it, 2 because I just don't remember, sorry. 3 Q. Sure. 4 A. So they -- they're saying 5 that the RiskMAP that's currently 6 approved for the cancer subset would have 7 to be broadened and -- because it may 8 increase the risk of inadvertent 9 exposure, as well as misuse. 10 And so they want to have the 11 RiskMAP be evaluated to consider the 12 increased risks. 13 Q. And did they have anything 14 to say at the meeting and in their 15 response about the current success of 16 the -- the success of the current RiskMAP 17 in place for Fentora? 18 MR. DIAMANTATOS: Objection 19 to form. 20 THE WITNESS: I can read 21 what is stated here. I don't have 22 a recollection. 23 It says, It is clear that 24 this program has not been entirely</p>	<p style="text-align: right;">Page 464</p> <p>1 THE WITNESS: It says "not 2 entirely successful," is how I see 3 it. 4 BY MR. CRAWFORD: 5 Q. But that was one of their 6 responses here. 7 So going down to the bottom 8 of that section, under discussion, with 9 respect to off-label use, it says, Dr. 10 Hertz stated that the sponsor had the 11 first RiskMAP of this kind with their 12 Actiq product, noting that the plan was 13 not very successful in limiting off-label 14 use. 15 So he's referring to the 16 whole Actiq RiskMAP and how it really was 17 not successful, right? 18 MR. DIAMANTATOS: Objection 19 to form. Calls for speculation. 20 Foundation. 21 THE WITNESS: That's how she 22 references this. 23 BY MR. CRAWFORD: 24 Q. And so it says that, The</p>
<p style="text-align: right;">Page 463</p> <p>1 successful, based on the known 2 postmarketing use patterns. 3 BY MR. CRAWFORD: 4 Q. All right. Let's read the 5 whole thing here. 6 It says -- at least the 7 first paragraph. The currently approved 8 RiskMAP was intended to minimize the risk 9 of overdose and death as a result of use 10 by improperly selected nonopioid-tolerant 11 patients, inappropriate use by noncancer 12 patients and inadvertent exposure of 13 household contacts. It is clear that 14 this program has not been entirely 15 successful, based on the known 16 postmarketing use patterns. 17 So in your view, and in this 18 meeting, was the FDA expressing to you 19 that it didn't think the current RiskMAP 20 was working with regard to stopping 21 inappropriate use by noncancer patients 22 as one element? 23 MR. DIAMANTATOS: Objection. 24 Form. Calls for speculation.</p>	<p style="text-align: right;">Page 465</p> <p>1 division cannot recommend how to better 2 formulate the plan. The sponsor must 3 propose new ways to address and manage 4 the risks of the product in the proposed 5 expanded population. 6 So it was putting the 7 burden, the FDA, on Cephalon to come up 8 with a viable plan that the FDA thought 9 could work to minimize the risk of abuse, 10 if it expanded the indication, right? 11 MR. DIAMANTATOS: Objection 12 to form. Foundation. Calls for 13 speculation. 14 THE WITNESS: That's how it 15 is stated here. 16 BY MR. CRAWFORD: 17 Q. So if you go to the next 18 page, the FDA is expressing some -- why 19 it's expressing reservations over 20 expanding the use, based on this -- 21 concerns about the RiskMAP here. 22 It does say, I'll just read 23 here at the bottom, The sponsor stated 24 that they have surveillance and education</p>

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<p style="text-align: center;">Page 466</p> <p>1 in the current plan, but the plan to 2 boost the educational portion of the plan 3 in regard to proper patient selection -- 4 I don't know if I'm reading that right. 5 Oh, okay. Strike that. 6 It states here, The FDA 7 stated that they have surveillance and 8 education in the current plan, but plan 9 to boost the educational portion of the 10 plan in regard to proper patient 11 selection. Dr. Hertz stated that they -- 12 or the agency agreed with this, but noted 13 that Actiq failed in this goal. 14 So the FDA is concerned 15 about expanding based on the bad 16 experience with Actiq, correct? 17 MR. DIAMANTATOS: Objection 18 to form. Foundation. Calls for 19 speculation. Mischaracterizes the 20 exhibit. 21 THE WITNESS: So it's kind 22 of strangely written. It says the 23 sponsor was going to boost it for 24 a noncancer indication. And Dr.</p>	<p style="text-align: center;">Page 468</p> <p>1 the -- the date is September 17th, 2008. 2 Actually, it was sent September 12th on 3 the back. 4 This was the FDA finding 5 that the request for a new expanded 6 indication to be not approvable, correct? 7 A. That's correct. 8 Q. Okay. So do you know if the 9 FDA ever approved an expanded indication 10 for Fentora for noncancer patients? 11 A. I believe they never did. 12 MR. CRAWFORD: Next I'm 13 going to mark Document 303. It's 14 going to be Exhibit-35. 15 - - - 16 (Whereupon, Teva-Marchione 17 Exhibit-35, 18 TEVA_MDL_A_00349300-301, was 19 marked for identification.) 20 - - - 21 BY MR. CRAWFORD: 22 Q. I think we're getting very 23 close to the end here. 24 So at some point, do you</p>
<p style="text-align: center;">Page 467</p> <p>1 Hertz stated that the agency 2 agreed with this, but noted that 3 Actiq failed in its goal. 4 Well, Actiq never -- we 5 never tried to get an expanded 6 indication. So it's kind of not 7 really written that correctly. 8 BY MR. CRAWFORD: 9 Q. Fair point. Yep. All 10 right. 11 MR. CRAWFORD: We'll mark 12 the next exhibit. 13 MR. JENSEN: 34. 14 - - - 15 (Whereupon, Teva-Marchione 16 Exhibit-34, TEV_FE00116840-843, 17 was marked for identification.) 18 - - - 19 BY MR. CRAWFORD: 20 Q. And this is the Exhibit-34, 21 TEV_FE00116840. This is -- this is 22 addressed to Ms. Levin, who is in your 23 department. 24 This is the FDA finding that</p>	<p style="text-align: center;">Page 469</p> <p>1 have a recollection -- I think we talked 2 about a REMS at the beginning of the 3 deposition, right, a risk evaluation 4 mitigation strategy? 5 A. Yes. 6 Q. Right. And at some point, 7 the FDA had indicated it wanted to impose 8 a REMS program on Actiq and Fentora, 9 correct? 10 MR. DIAMANTATOS: Objection. 11 Form. 12 THE WITNESS: A REMS? So 13 it's a timing issue. I don't know 14 if they ever wanted to get a REMS 15 on Actiq, because we stopped 16 marketing by the time the REMS 17 came into place. 18 But yes for Fentora. 19 BY MR. CRAWFORD: 20 Q. All right. And were you or 21 the company involved in spearheading any 22 effort to -- for the industry to put 23 together a proposed REMS for the FDA? 24 A. So that was at the time when</p>

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<p style="text-align: right;">Page 470</p> <p>1 I -- my new manager, Jim Ottinger, came. 2 So I -- I was asked to kind of help him 3 get up to speed, because he was the 4 person spearheading that. So I worked a 5 couple months overlapping with him on 6 that.</p> <p>7 Q. What was his name again? 8 A. Jim Ottinger, James 9 Ottinger. He was the vice president of 10 regulatory.</p> <p>11 Q. How do you spell his last 12 name? 13 A. O-T-T-I-N-G-E-R.</p> <p>14 Q. And he was leading an effort 15 to -- collaboration with the other drug 16 makers that made that class of drugs, the 17 TIRF REMS, right, or the TIRF products to 18 prepare a REMS, right?</p> <p>19 A. Let me -- I'm sorry, let me 20 just back up. 21 It was a transition between 22 Eric Floyd, who left, and then Jim 23 Ottinger came. So I think at that point, 24 Eric Floyd was leading that, left, they</p>	<p style="text-align: right;">Page 472</p> <p>1 MR. DIAMANTATOS: Objection 2 to form. Foundation. 3 THE WITNESS: When this 4 started, I was not -- when -- an 5 expansion came more, I believe, 6 from the FDA than from us. 7 So my recollection, and 8 please, you know, it was a time 9 when I was transitioning off of 10 the program, I was under the 11 impression that the FDA was the 12 one that was trying to put a class 13 together, because -- so every 14 single manufacturer wouldn't have, 15 you know, to go through having 16 physicians attest to something. 17 So I could be wrong. But I 18 thought it was the FDA who was 19 trying to group it, or maybe 20 discussions with different 21 manufacturers, because -- for 22 consistency.</p> <p>23 BY MR. CRAWFORD: 24 Q. So the manufacturers were</p>
<p style="text-align: right;">Page 471</p> <p>1 asked me to kind of cover for him until 2 Jim Ottinger, my new manager, got up to 3 speed to take that over. 4 Q. And was this Teva, at this 5 time, it was -- well, it wasn't Teva. 6 It may have still been 7 Cephalon, right? 8 A. Yeah, I think it -- I think 9 it was Teva. It was around that 10 transition time, yes. 11 Q. So Teva or Cephalon were 12 leading the effort, amongst this class of 13 drugs and manufacturers, to prepare and 14 propose a REMS for the FDA? 15 A. You know, I'm trying to 16 remember -- 17 MR. MUDGE: Object to form. 18 BY MR. CRAWFORD: 19 Q. Let me back up and strike 20 that. 21 So there was some kind of 22 group formed of manufacturers, right, to 23 do something with regard to the REMS, 24 right?</p>	<p style="text-align: right;">Page 473</p> <p>1 all operating independently in 2 interfacing with the FDA, or was there 3 kind of a unified group working together 4 on the manufacturers' side? 5 MR. DIAMANTATOS: Objection. 6 Form. Foundation. Calls for 7 speculation. 8 THE WITNESS: So, obviously, 9 initially, it was -- manufacturers 10 were working individually. And I 11 don't know who led -- or who had 12 the understanding to make it into 13 a group. 14 In my recollection, I 15 thought it was initiated by the 16 FDA. But because I was not as 17 involved at that point, I'm 18 probably not the best person to 19 answer that. But that was my 20 understanding. 21 So all the stopgaps that we 22 were putting in to the chain of 23 events, it would be consistent 24 amongst all the manufacturers</p>

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<p style="text-align: right;">Page 474</p> <p>1 doing the same thing. And I 2 think -- so I think that was the 3 issue, and it wouldn't be 4 repetitive as much for a doctor to 5 have to do multiple -- everything 6 in the short-acting class or 7 whatever. That was my 8 recollection.</p> <p>9 BY MR. CRAWFORD:</p> <p>10 Q. Yeah. I'm just trying to 11 find out if there was a group of 12 manufacturers that were working together 13 to make some proposals to the FDA?</p> <p>14 A. So I remember --</p> <p>15 MR. DIAMANTATOS: Objection 16 to form. Foundation. Asked and 17 answered. Speculation. Vague.</p> <p>18 THE WITNESS: I remember, 19 actually, Sharon Hertz asking us 20 to go and talk to other 21 manufacturers. And it was -- it 22 was kind of soft, because they 23 didn't legally have the ability to 24 make you work together.</p>	<p style="text-align: right;">Page 476</p> <p>1 Q. Okay. That's fine. 2 So we marked here as 3 Exhibit-35 a timeline here, 4 TEVA_MDL_A_00349300. 5 This is just a timeline we 6 found in the Teva documents called, 7 Timeline of Events Leading Up to the REMS 8 Requirement For Opioid Analgesics. 9 And I thought maybe this is 10 a good shortcut to trigger your memory of 11 the steps and processes that were 12 undertaken here. 13 So the first point that I 14 wanted you to look at, just for 15 reference, September 25th, 2006, says, 16 Fentora fentanyl buccal tablet approved 17 for use in breakthrough pain in 18 opioid-tolerant patients with cancer. 19 So that at least provides us 20 a guide point. That's an accurate date, 21 correct? 22 A. I believe so. 23 Q. And then -- and then June 24 22nd, 2007, it says, Fentora pre-SNDA</p>
<p style="text-align: right;">Page 475</p> <p>1 But I remember saying, well, 2 how can we do that? And the more 3 I think about it, the more it was 4 directed by the FDA.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. All right. But there was a 7 group that got together and worked on it, 8 of manufacturers?</p> <p>9 MR. DIAMANTATOS: Objection. 10 Form. Foundation. Asked and 11 answered repeatedly. Calls for 12 speculation.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. If you know.</p> <p>15 A. I think -- I know we started 16 talking to one of them, you know, because 17 they -- they kind of prompted -- they 18 kept prompting us to do that.</p> <p>19 And, again, that's about the 20 time I went off the project.</p> <p>21 Q. And you say talked to "one 22 of them," one of the other manufacturers?</p> <p>23 A. Yeah. And I can't remember 24 which one.</p>	<p style="text-align: right;">Page 477</p> <p>1 call with the FDA to discuss SNDA risk 2 minimization action plan, RiskMAP, when 3 FDA indicated concerns whether or not the 4 approved RiskMAP was as effective as 5 possible. Concerns arose because of new 6 information regarding the safety of 7 Fentora, including reports of a death of 8 a patient who was not opioid tolerant and 9 taking Fentora for a migraine, conversion 10 from Actiq to Fentora, substitution at 11 pharmacy and patients not understanding 12 dosing. 13 So do you recall, during 14 this June 2007 time period, the FDA 15 raising these concerns?</p> <p>16 MR. DIAMANTATOS: Objection 17 to form. Foundation.</p> <p>18 THE WITNESS: I was 19 obviously on the project at the 20 time. I just don't remember that 21 specific incident.</p> <p>22 BY MR. CRAWFORD:</p> <p>23 Q. All right. And then in 24 August, they're talking about, Cephalon</p>

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<p>1 notified of additional reports of deaths 2 due to the same reasons as June 22nd 3 discussion with FDA. 4 Do you recall that 5 notification? 6 MR. DIAMANTATOS: Objection 7 to form. Foundation. 8 THE WITNESS: You know, I 9 don't remember. 10 BY MR. CRAWFORD: 11 Q. All right. Skipping ahead, 12 the next page, to March 27th, 2008. 13 It states, FDA issues 14 federal register that identifies Actiq as 15 one of the 16 drugs needing a REMS by 16 September 21st. 17 Do you see that? 18 A. I do see that. 19 Q. Does that refresh your 20 recollection that maybe the FDA wanted a 21 REMS for Actiq? 22 MR. DIAMANTATOS: Objection 23 to form. Foundation. 24 THE WITNESS: I believe I</p>	<p>1 it was never approved, and a REMS will be 2 now substituted instead. 3 Do you recall withdrawing 4 the amended RiskMAP for Actiq in '09? 5 MR. DIAMANTATOS: Objection. 6 Form. Foundation. 7 THE WITNESS: No, I don't. 8 BY MR. CRAWFORD: 9 Q. And April 2nd, 2009, states, 10 Cephalon submits proposed REMS for Actiq 11 and proposed REMS for Fentora to the FDA. 12 Were you involved at all in 13 preparation of a submission of a proposed 14 REMS for Actiq and Fentora around this 15 April 2009 time period? 16 A. Not that I can recall. 17 MR. CRAWFORD: Let's mark 18 the next exhibit. That would be 19 632. 20 - - - 21 (Whereupon, Teva-Marchionne 22 Exhibit-36, 23 TEVA_MDL_A_00651161-168, was 24 marked for identification.)</p>
<p>1 was off the project by then. And 2 to be honest, I didn't even 3 remember if Actiq was still on the 4 market -- you know, I thought 5 they -- I didn't know -- they 6 weren't promoting it, maybe. It 7 was on the market. But I just 8 don't remember that. 9 BY MR. CRAWFORD: 10 Q. All right. And then 11 September 17th, 2008, Cephalon submits 12 initial REMS proposal for Actiq to the 13 FDA. 14 Were you involved at all in 15 that submission to the FDA? 16 A. Not that I can recall. 17 Q. All right. February 6, 18 2009, FDA informs 15 drug manufacturers 19 that will require a REMS for certain 20 opioid drug products to ensure safe use. 21 Do you recall that at all? 22 A. No, I don't. 23 Q. March 3rd, 2009, Cephalon 24 withdraws the amended RMP for Actiq since</p>	<p>1 - - - 2 BY MR. CRAWFORD: 3 Q. So we marked now a June 4 11th, 2010 letter from you to Dr. 5 Rappaport stating -- it's document 6 TEVA_MDL_A_00651161. 7 It states, At the request of 8 the agency, Cephalon representatives met 9 with FDA on May 25th, 2010, with the 10 intention of resolving outstanding issues 11 related to the REMS for both Actiq and 12 Fentora so that these strategies can be 13 implemented as soon as possible. The 14 submission contains Cephalon's minutes of 15 the discussions during the May 25th 16 meeting. 17 And it's signed by you. 18 So was this -- do you recall 19 now being involved in these discussions 20 around June 2010 time period? 21 MR. DIAMANTATOS: Objection 22 to form. 23 THE WITNESS: I do recall 24 now. This is when I was pulled</p>

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<p>1 back -- let me see. Who was 2 there? 3 This is when Jim Ottinger 4 first came. This was that period. 5 Yes, I do recall this.</p> <p>6 BY MR. CRAWFORD:</p> <p>7 Q. So you were involved in 8 discussions with the FDA about the Actiq 9 and Fentora REMS and getting that in 10 place?</p> <p>11 A. I was on the transition team 12 during this, yes.</p> <p>13 Q. And if you look at the last 14 page, it looks like you had attended the 15 meeting as senior director and group 16 leader, regulatory affairs, Cephalon, 17 correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And you attended with Jim 20 Ottinger, right? That was when you were 21 helping him transition on this, right?</p> <p>22 A. That's correct, yes.</p> <p>23 Q. So that fits within your 24 recollection. But at least it gives us a</p>	<p>1 about it, I need you to show her 2 the entirety of the exhibit so she 3 can review it and comment on it. 4 Flashing it on the screen is not 5 good enough.</p> <p>6 MR. CRAWFORD: How about if 7 I get her to acknowledge and not 8 ask her questions about the 9 document?</p> <p>10 MR. DIAMANTATOS: No. If 11 you're going to ask her any 12 questions about a document, she 13 has to be given the opportunity to 14 review it.</p> <p>15 I'm not trying to be 16 difficult. If you want to take 17 the time to go through it on the 18 screen page by page and give the 19 witness the ample opportunity to 20 review it appropriately so she can 21 intelligently answer your 22 questions, I don't necessarily 23 have an objection to that, since 24 you don't have a paper copy.</p>
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<p>1 time period. 2 You were involved here in 3 this 2010 time period, right?</p> <p>4 A. Right.</p> <p>5 MR. CRAWFORD: So now we're 6 going to mark as Exhibit-587 -- 7 I'm sorry, Document 587, that will 8 be Exhibit-37. And then we're 9 going to attach to that two 10 documents which were attachments, 11 the Actiq REMS and the Fentora 12 REMS.</p> <p>13 I don't have a copy of the 14 Actiq REMS. I just have the 15 electronic copy. But I want to 16 kind of get these into the record, 17 since it's regulatory and she's 18 our regulatory person.</p> <p>19 So I'm going to flash it on 20 the screen and see if counsel is 21 agreeable to my --</p> <p>22 MR. DIAMANTATOS: If you're 23 going to show her an exhibit and 24 intend on asking her questions</p>	<p>1 MR. CRAWFORD: Let's do 2 that, then. 3 - - - 4 (Whereupon, Teva-Marchione 5 Exhibit-37, 6 TEVA_MDL_A_07679381-383, was 7 marked for identification.) 8 - - - 9 (Whereupon, Teva-Marchione 10 Exhibit-38, 11 TEVA_MDLA_A07679384-521, was 12 marked for identification.) 13 - - - 14 MR. CRAWFORD: So 587 is 15 Exhibit-38. And then the Actiq 16 REMS, we'll get a hardcopy, will 17 be 39. And then the Fentora REMS 18 is 40, because that's how the 19 document numbers go sequentially.</p> <p>20 BY MR. CRAWFORD: 21 Q. After that meeting with the 22 FDA and Mr. Ottinger was involved, did 23 you kind of drop off the REMS project? 24 A. Yes, that's correct.</p>

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<p>1 Q. So you weren't around for 2 the actual finalization of the REMS plan, 3 right? 4 A. Not that I can recall. I 5 don't think I was. 6 Q. And did Mr. Ottinger, by 7 that point, take over kind of the duties 8 for the company with regard to the final 9 negotiations with the FDA on the REMS?</p> <p>10 MR. DIAMANTATOS: Objection. 11 Form. Foundation.</p> <p>12 THE WITNESS: I don't 13 remember. I'm seeing Susan 14 Frank's name here, so she may have 15 done that.</p> <p>16 BY MR. CRAWFORD:</p> <p>17 Q. And so we marked here 37. 18 This is an e-mail. 19 I don't see you on this 20 e-mail, 37, but it's attaching the two 21 REMS documents that we marked as 22 Exhibit-38 and 39, or we will mark for 38 23 for Actiq. 24 Take a look at 39. I just</p>	<p>1 TEVA_MDL_A_07679384. 2 BY MR. CRAWFORD: 3 Q. That document states that, 4 This supplemental new drug application 5 proposes modifications to the approved 6 Fentora -- REMS for Fentora. We have 7 completed our review of this supplemental 8 application as amended. It is approved, 9 effective on the date of this letter, for 10 use as recommended in the enclosed, 11 agreed-upon labeling text. 12 So 38 is, you would agree, 13 from your regulatory experience, I know 14 you're not on the e-mail, but that would 15 be an FDA approval of the REMS, right, 16 for Fentora. 17 A. That's my understanding. 18 MR. DIAMANTATOS: Objection 19 to form. 20 BY MR. CRAWFORD: 21 Q. And then 40, is that the 22 missing one? 23 MR. JENSEN: 39 is the 24 missing one.</p>
<p style="text-align: right;">Page 487</p> <p>1 want to see, from your regulatory 2 experience, does that look like an FDA 3 approval of a REMS, at least for Fentora, 4 Exhibit-39?</p> <p>5 A. Yes, it does. 6 Q. Okay. All right. I'm 7 having a little confusion here about what 8 we've attached, and I apologize. 9 So this e-mail chain, what 10 exhibit is that? Do you have marked 11 there on your right hand? 12 A. The e-mail chain is 037. 13 Q. So that's 37. And then we 14 marked --</p> <p>15 MR. DIAMANTATOS: Just to be 16 clear, do you want to say the 17 Bates for the record?</p> <p>18 MR. CRAWFORD: Yes, that's 19 good. Thank you. I think that 20 will make it clear. 21 TEVA_MDL_A_07679381. 22 And then what follows 23 sequentially is Exhibit 38, which 24 I believe is an attachment,</p>	<p style="text-align: right;">Page 489</p> <p>1 MR. CRAWFORD: 39, sorry. 2 Can we bring up 39 on the 3 screen? 4 BY MR. CRAWFORD: 5 Q. I think it's just a similar 6 one. 7 And I want to ask you the 8 same question, if that looks to you like 9 an approval. And you're welcome to flip 10 through as many pages as you want until 11 you feel comfortable that it would be an 12 approval of the Actiq REMS. 13 And he's going to bring it 14 up on the screen. 15 And that's all I'm going to 16 ask you about that, because you weren't 17 present at the time? 18 A. No, I wasn't. 19 MR. CRAWFORD: Why don't we 20 come back to that? 21 I want to mark the next 22 exhibit, which is Document 635. 23 MR. JENSEN: Exhibit-40. 24 - - -</p>

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<p style="text-align: center;">Page 490</p> <p>1 (Whereupon, Teva-Marchione 2 Exhibit-40, 3 TEVA_MDL_A_08261145.xls, was 4 marked for identification.) 5 - - - 6 BY MR. CRAWFORD: 7 Q. Now, when you were heading 8 up that regulatory department, did you 9 keep -- was there a call log or a contact 10 log with the FDA that was kept in the 11 department? 12 A. There was. There was some 13 informal calls, I think -- yes. When 14 there were formal telecons and meetings, 15 there was a document that we would fill 16 out. 17 I believe, though, informal 18 calls we also logged, to the best of my 19 recollection. 20 MR. CRAWFORD: And can we 21 have a copy of the exhibit for the 22 witness, please? 23 MR. JENSEN: She has it. 24 BY MR. CRAWFORD:</p>	<p style="text-align: center;">Page 492</p> <p>1 correspondence, at least, that should be 2 reflected in the logs that were kept with 3 the department, right? 4 MR. DIAMANTATOS: Objection 5 to form. Foundation. Calls for 6 speculation. 7 THE WITNESS: That's the 8 process. 9 BY MR. CRAWFORD: 10 Q. So you had voiced some 11 concern that DDMAC kept changing its 12 demands on what it wanted on promotional 13 materials. 14 If that was in 15 correspondence, that should be reflected 16 in this official correspondence log, 17 right? 18 A. So that was the details that 19 were in the letter. When we -- I 20 expressed those concerns at that meeting. 21 Before then, we never -- I don't know if 22 I actually wrote to them and expressed 23 the concern. 24 So it's -- the details are</p>
<p style="text-align: center;">Page 491</p> <p>1 Q. We marked Exhibit-40, which 2 is TEVA_MDL_A_08261145.xls. 3 So this appears to be, what 4 it states is, Actiq official 5 correspondence log. Starting with 6 11/11/96, and it goes through 3/8/2005. 7 Does this look familiar to 8 you as a type of correspondence log that 9 was kept for your department? 10 A. I mean, probably. So many 11 of these logs that you deal with. So it 12 looks reasonable. 13 Q. So it was the practice of 14 your department, during the entire time 15 you were there, to keep some kind of log 16 of contacts and communications with the 17 FDA? 18 A. Yes, that's correct. 19 Q. And here there are -- you do 20 keep a log of submissions of promotional 21 materials to DDMAC, right? 22 A. That's correct. 23 Q. So if there was any 24 back-and-forth with DDMAC, and</p>	<p style="text-align: center;">Page 493</p> <p>1 within -- when you see the conflicting 2 information, you have to look at each of 3 the MACMIS numbers that are there, you 4 see MACMIS ID. 5 So every time we submitted 6 the document, we got an MACMIS number. 7 Q. What is an MACMIS? 8 A. It's a numbering system from 9 the FDA, from DDMAC. 10 Q. You're pointing to something 11 on Exhibit-40. 12 What are you pointing to? 13 A. Oh, like -- 14 Q. Here it is. The submission 15 number? 16 A. Right. 17 Q. So, anyway, if it was in 18 writing, an exchange between DDMAC and 19 you, it should show up in this log, 20 right? 21 A. It should, yes. 22 Q. So when you're talking about 23 stuff that may have been transmitted in 24 writing that you were concerned about</p>

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<p style="text-align: right;">Page 494</p> <p>1 later and addressed with them verbally, 2 that dealt with these past MACMIS 3 exchanges, right? 4 A. Correct. 5 You would have -- you would 6 have to go into a specific one and 7 show -- they would tell you to do one 8 thing and they would have to find another 9 one to say that they reversed their 10 issues. 11 Q. All right. 12 MR. CRAWFORD: I got one 13 more exhibit to attach. That 14 would be 570. 15 MR. JENSEN: Exhibit-41. 16 - - - 17 (Whereupon, Teva-Marchione 18 Exhibit-41, 19 TEVA_MDL_A_08475177-178, was 20 marked for identification.) 21 - - - 22 BY MR. CRAWFORD: 23 Q. Did you ever do any kind of 24 analysis, while you were at Teva or</p>	<p style="text-align: right;">Page 496</p> <p>1 please call to discuss? I have a review 2 meeting today on this, and I wanted to 3 talk to you before that meeting, if 4 possible. Thanks, Carol. 5 So do you recall anything 6 about dealing with reprints around this 7 2009 time period and having review 8 meetings? 9 A. Let me see. 10 So I remember that the 11 compliance group that was supporting the 12 CIA wanted to have a policy about reprint 13 dissemination, and I went to a meeting 14 where they were proposing a policy. 15 Q. And it was about this 2009 16 time period? 17 A. I believe so. 18 Q. And did you -- do you recall 19 anything about that meeting, any details? 20 MR. DIAMANTATOS: Objection 21 to form. 22 THE WITNESS: So when they 23 proposed a policy, I don't know if 24 I necessarily agreed with the</p>
<p style="text-align: right;">Page 495</p> <p>1 Cephalon, about reprints and how they 2 should be used to comply with 3 regulations, reprints of journal 4 articles? 5 MR. DIAMANTATOS: Objection 6 to form. 7 THE WITNESS: Excuse me, I 8 don't understand specifically what 9 to do with reprints -- 10 BY MR. CRAWFORD: 11 Q. Yes. Advising the company 12 on what the regulations were with 13 disseminating reprints, under FDA 14 regulations. 15 MR. DIAMANTATOS: Objection 16 to form. Foundation. 17 BY MR. CRAWFORD: 18 Q. We've marked here 19 Exhibit-41. 20 It's an e-mail from you to 21 Eric Floyd, Forward: Good reprint 22 practices, review team. 23 You state, Eric, if you have 24 a break from your meeting, could you</p>	<p style="text-align: right;">Page 497</p> <p>1 policy. And I was asked just to 2 kind of improve it, and it was -- 3 I think -- I think the 4 understanding was that the 5 compliance group had a deadline to 6 meet and, you know, they didn't 7 want a lot of back-and-forth on 8 the policy, which I didn't 9 necessarily agree with all the 10 components. 11 And so I -- I wanted to 12 alert my manager that, you know, 13 this may be an issue, so I just 14 wanted to talk to him. 15 BY MR. CRAWFORD: 16 Q. Just the final thing, let's 17 throw up 39, which I just wanted to see 18 if you agree that that looks to you like 19 the FDA approving the Actiq REMS in the 20 supplemental approval, similar to the 21 Fentora one that was attached. 22 And, again, we'll get a 23 hardcopy, an electronic copy, to the 24 court reporter on that, and counsel.</p>

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1	MR. CRAWFORD: Forward a 2 copy to counsel here, and the 3 court reporter.	1 begin these examinations with an 2 objection. So I'll lodge my 3 standard objection with the record 4 that we object to the deposition 5 going forward on behalf of my 6 Tennessee clients, for Teva's 7 failures to meet its obligations 8 under the state, federal 9 cooperation protocol, as we've 10 laid out in our previous 11 depositions and in our motion to 12 quash.
13	BY MR. CRAWFORD: 14 Q. What we have here is a -- 15 MR. CRAWFORD: Can we go 16 down to the date? Scroll down. 17 THE WITNESS: The date is 18 actually the last page. 19 MR. DIAMANTATOS: I'll note 20 for the record this is a 142-page 21 document. 22 BY MR. CRAWFORD: 23 Q. Right. 12/28/11. 24 It's similar to the other Fentora one that was attached, I'll represent. If you want to scroll through it, but all I want to ask is, does this look like the approval for the	13 BY MR. GASTEL: 14 Q. Subject to that objection, I 15 am going to have some questions for you. 16 I'll be a lot shorter than Mr. Crawford's 17 examination throughout the day. As I stated, the people that I represent are in the state of Tennessee. So I'll begin with a question that, for your work for Cephalon and later Teva, did you ever have an opportunity to travel to the state of
1	Page 499	Page 501
2	REMS for Actiq? A. Yes, it does. 3 MR. CRAWFORD: That's all I 4 have. And I pass the witness. 5 Thank you. 6 THE WITNESS: Thank you. 7 VIDEO TECHNICIAN: Going off 8 the record at 5:56 p.m. 9 - - - 10 (Whereupon, a brief recess 11 was taken.) 12 - - - 13 VIDEO TECHNICIAN: We're 14 back on the record at 6:01 p.m. 15 - - - 16 EXAMINATION 17 - - - 18 BY MR. GASTEL: 19 Q. Good evening, Ms. Marchione. 20 My name is Ben Gastel, and I 21 represent a group of plaintiffs in the 22 state of Tennessee that have been 23 cross-noticed into this deposition today. 24 MR. GASTEL: We normally	1 Tennessee? 2 A. I don't think so, no. 3 Q. Did you ever review any 4 records of the Tennessee Department of 5 Health related to Tennessee's opioid 6 crisis? 7 MR. DIAMANTATOS: Objection 8 to form. 9 Go ahead. 10 THE WITNESS: No, I haven't. 11 BY MR. GASTEL: 12 Q. Do you have any 13 understanding, as you sit here today, 14 about prescription -- about rates of 15 prescriptions for prescription opioids in 16 the state of Tennessee? 17 A. No, I do not. 18 Q. We've looked at a lot of 19 documents today showing concerns by 20 Cephalon, Teva and the FDA about abuse 21 and misuse of opioids. 22 Throughout your role as 23 director of regulatory affairs with Teva and Cephalon, you knew that there were

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<p>1 problems with abuse and misuse of opioids 2 throughout the country, right? 3 MR. DIAMANTATOS: Objection 4 to form. 5 Go ahead. 6 THE WITNESS: Generally, 7 yes. 8 BY MR. GASTEL: 9 Q. And that would include abuse 10 and misuse of prescription opioids in 11 states like Tennessee, right? 12 MR. DIAMANTATOS: Objection 13 to form. 14 Go ahead. 15 THE WITNESS: Not 16 specifically. But in general, 17 country-wide. 18 BY MR. GASTEL: 19 Q. You went through the Fentora 20 RiskMAP with Mr. Crawford earlier today, 21 and he read you a portion of that that 22 referenced geographic hotspots. 23 Do you remember that 24 document and that testimony?</p>	<p>1 MR. GASTEL: I've got a copy 2 for you, counsel. 3 THE WITNESS: Thank you. 4 BY MR. GASTEL: 5 Q. And you'll see, Ms. 6 Marchione, that this is an e-mail 7 correspondence from July of 2006. 8 Do you see that? 9 A. I do, yes. 10 Q. And it's an e-mail from 11 Simon Diaz to you, dated July 21st, 2006, 12 with the subject line, Hydrocodone ER. 13 Do you see that? 14 A. Yes. 15 Q. Do you recall receiving this 16 e-mail? 17 A. No. 18 Q. It's forwarding an e-mail 19 from Iris Luo, sent to a variety of 20 folks. And it says, Hi Team. 21 Do you see that, ma'am? 22 A. I do, yes. 23 Q. And the e-mail says, Thank 24 you for participating in the evaluation</p>
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<p>1 A. I remember that phrasing, 2 yes. 3 Q. Do you know if Cephalon or 4 Teva considered Tennessee a geographic 5 hotspot for abuse? 6 A. Nothing was ever mentioned 7 specifically about any particular 8 hotspots to me. 9 Q. Do you know what metric is 10 used to determine a geographic hotspot 11 for prescription opioid abuse? 12 MR. DIAMANTATOS: Objection. 13 Form. Foundation. 14 THE WITNESS: No, I do not. 15 BY MR. GASTEL: 16 Q. I'm going to hand you a 17 document that we're going to mark as 18 Exhibit-42. 19 - - - 20 (Whereupon, Teva-Marchione 21 Exhibit-42, 22 TEVA_MDL_A_08380029-030, was 23 marked for identification.) 24 - - -</p>	<p>1 of the hydrocodone ER program from ELAN. 2 Did I read that correctly? 3 A. I think so. 4 Q. Do you recall this 5 hydrocodone ER program from ELAN that's 6 referenced in this e-mail that was 7 forwarded to you back in 2006? 8 A. No, I do not. 9 Q. The e-mail you were 10 forwarded goes on to state, After the 11 recent commercial review, we have decided 12 not to move forward with this 13 opportunity, due to several concerns. 14 First and foremost, the product itself 15 doesn't possess any abuse deterrent 16 feature and any mechanism to prevent 17 alcohol dumping that the regulatory 18 agency prefers to see these days for 19 LAOs. 20 Did I read that correctly? 21 A. Yes, you did. 22 Q. Is the reference there to -- 23 of "LAOs," long-acting opioids? 24 A. I'm deducing that it is.</p>

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<p>1 Q. And was it your 2 understanding that, at this time -- and 3 do you believe that the "regulatory 4 agency" there is a reference to the FDA?</p> <p>5 MR. DIAMANTATOS: Objection 6 to form. Foundation. Calls for 7 speculation.</p> <p>8 THE WITNESS: Because it's 9 in the U.S. -- because, I 10 think ELAN is in the U.S., I'm 11 deducing it would be the FDA.</p> <p>12 BY MR. GASTEL:</p> <p>13 Q. Sure. So do you recall that 14 the FDA was concerned, back in 2006, 15 about only approving hydro -- 16 prescription opioids containing 17 hydrocodone if they also contained an 18 abuse-deterrent feature?</p> <p>19 A. Deterrent --</p> <p>20 MR. DIAMANTATOS: Objection 21 to form and foundation.</p> <p>22 Go ahead.</p> <p>23 THE WITNESS: No. I mean, I 24 know that abuse deterrence was</p>	<p>1 correct? 2 A. That's correct. 3 Q. And then at some point, 4 Cephalon merges with Teva; is that your 5 understanding?</p> <p>6 MR. DIAMANTATOS: Objection 7 to form.</p> <p>8 THE WITNESS: No. Teva 9 acquired Cephalon.</p> <p>10 BY MR. GASTEL:</p> <p>11 Q. Sure. And then at that 12 point, you ceased being a Cephalon 13 employee and you became a Teva employee?</p> <p>14 A. That's correct. 15 - - - 16 (Whereupon, Teva-Marchione 17 Exhibit-43, TEVA_MDL_A_03130348, 18 was marked for identification.) 19 - - - 20 BY MR. GASTEL: 21 Q. I'm going to hand you a 22 document that we'll mark as Exhibit-43. 23 MR. DIAMANTATOS: Thank you. 24 THE WITNESS: Thank you.</p>
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<p>1 starting to be a big plus at that 2 time.</p> <p>3 But this is -- the person 4 who is saying that is from the 5 business development group, so 6 that's not really her area of 7 expertise. So, you know, she 8 probably was referring to what was 9 in the local news, or whatever.</p> <p>10 BY MR. GASTEL:</p> <p>11 Q. Sure. And the reason why 12 abuse deterrents were picking up around 13 this time was because the widespread 14 abuse of prescription opioids throughout 15 the country, right?</p> <p>16 MR. DIAMANTATOS: Objection. 17 Form. Foundation. Argumentative. 18 Assumes facts.</p> <p>19 THE WITNESS: Again, I would 20 have to assume, in general, that 21 that was the case.</p> <p>22 BY MR. GASTEL:</p> <p>23 Q. And at this time in 2006, 24 your formal employer was Cephalon,</p>	<p>1 BY MR. GASTEL: 2 Q. And I'll represent to you 3 that this is an e-mail from Cynthia Arons 4 dated October 9th, 2015. 5 It doesn't have a "to" line, 6 but the subject line is, CCALC meeting 7 minutes, final comment period for bylaws. 8 Do you see that? 9 A. I do see that. 10 Q. And I'll represent to you 11 that this first page, ma'am, represents 12 the metadata that's associated with this 13 e-mail. And it shows up in your 14 custodial file and that you're the 15 custodian of this. 16 Is it possible that you were 17 blind carbon-copied on this e-mail and 18 that's why it's showing up in your 19 custodial file? 20 MR. DIAMANTATOS: Objection. 21 Form. Foundation. 22 THE WITNESS: I left the 23 company in 2013. 24 BY MR. GASTEL:</p>

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1	Q. Sure.	A. That's correct.
2	A. So I have no idea.	Q. Are you familiar with SNDAs,
3	Q. Yeah. It kind of puzzled	or supplemental new drug applications?
4	us, too.	A. Yes, that's correct.
5	Do you know what the CCALC	Q. Who gets to decide if a
6	is?	product is ultimately approved?
7	A. No. I was trying to	A. The FDA.
8	determine that, but I don't -- I don't	Q. Who gets to decide if a
9	know.	product will -- approval will be pulled?
10	Q. Does the term Cross-Company	A. FDA.
11	Abuse Liability Council ring any bells in	Q. Does a pharmaceutical
12	your mind?	company get to decide that?
13	A. No, it doesn't.	A. No, they do not.
14	Q. Do you ever recall reviewing	Q. You were asked a series of
15	meeting minutes or the bylaws for that	questions --
16	organization?	A. Excuse me. There are times
17	A. No, I do not.	when a pharmaceutical company can pull
18	MR. GASTEL: Ms. Marchione,	product on their own.
19	I told you I would be very short.	Q. So voluntarily a
20	That is the end of my examination.	pharmaceutical company can decide to pull
21	Subject to our previous objection	a product, correct?
22	and any need that we might need to	A. That's correct, yes.
23	have to recall you, that's all the	Q. But as far as the FDA
24	questions we have, and we'll	approval, am I correct that the final say
	Page 511	Page 513
1	reserve.	so, in terms of that approval, is, of
2	THE WITNESS: Thank you.	course, the FDA?
3	VIDEO TECHNICIAN: Going off	A. Yes, that's correct.
4	the record at 6:11 p.m.	Q. You were asked a series of
5	- - -	questions with regard to the FDA taking
6	(Whereupon, a brief recess	issue with Cephalon and then, later, Teva
7	was taken.)	with the RiskMAP program.
8	- - -	Do you recall those
9	VIDEO TECHNICIAN: Back on	questions?
10	the record at 6:14 p.m.	A. Yes, I do.
11	- - -	Q. How would you describe the
12	EXAMINATION	dialogue that you engaged with the FDA in
13	- - -	those instances?
14	BY MR. DIAMANTATOS:	A. Very interactive. Cordial.
15	Q. Ms. Marchione, you were	That's it.
16	asked a series of questions this morning	Q. At any point in time, did
17	and afternoon by counsel with regard to	you refuse to give the FDA information
18	your role at Cephalon, and later Teva,	that they were seeking?
19	and your interactions with the FDA.	A. Never.
20	You're familiar with the FDA	Q. At any point in time, did
21	approval process insofar as what	you refuse to attend a meeting that the
22	pharmaceutical companies are expected to	FDA had requested?
23	submit as part of their new drug	A. No.
24	applications, correct?	Q. Do you have any knowledge of

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<p style="text-align: right;">Page 514</p> <p>1 anyone from your team, or at Cephalon or 2 Teva, receiving such a request from the 3 FDA? 4 A. No, not at all. 5 Q. To either provide 6 information -- 7 A. That's correct. 8 Q. -- or sit down for a 9 meeting? 10 A. Always, we were always 11 there. 12 Q. You detailed for us earlier 13 this morning and afternoon, during the 14 approximate 2003 to 2004 time frame, 15 there was specific dialogue with the FDA 16 about concerns that were raised having to 17 do with Actiq in particular, correct? 18 A. That's correct. 19 Q. You detailed for us that 20 there was a meeting that culminated with 21 Cephalon asking for a sit-down and a July 22 12th, 2004 presentation, which in the 23 record is Exhibit-11. 24 Do you recall that?</p>	<p style="text-align: right;">Page 516</p> <p>1 Q. And you acknowledged that 2 you passed on that message to other team 3 members of yours at Cephalon, correct? 4 A. That's correct. 5 Q. And that this culminated in 6 a sit-down meeting with Mr. Rappaport and 7 others from the FDA, correct? 8 A. That's correct. 9 Q. That meeting happened some 10 time in 2004? 11 A. That's correct. July -- 12 what was it? The meeting was scheduled 13 for July 14, 2004. 14 Q. And that meeting, of course, 15 occurred, and you testified about it 16 earlier today, right? 17 A. Yes, I did. 18 Q. The approximate 682 pages 19 that make up Exhibit-11, what is that, in 20 Exhibit-11? 21 A. That was a meeting package 22 that the FDA specifically asked for, for 23 different pieces, that we provided prior 24 to the meeting.</p>
<p style="text-align: right;">Page 515</p> <p>1 MR. CRAWFORD: Objection. 2 Form. Mischaracterizes. 3 BY MR. DIAMANTATOS: 4 Q. Do you recall being shown an 5 Exhibit-11? And it should be in front of 6 you, and if you can pull it out, that 7 would be great. 8 MR. DIAMANTATOS: For the 9 record, I'll note that it's Bates 10 TEVA_MDL_A_01575289 through 11 TEVA_MDL_A_01575971. 12 THE WITNESS: Yes. 13 And just to be clear, you 14 just said that we asked for a 15 sit-down. It was the other way 16 around, the FDA asked us to come 17 out. 18 BY MR. DIAMANTATOS: 19 Q. So Mr. Rappaport reached out 20 to you, right? 21 And we saw that in an 22 exhibit, with regard to the concerns that 23 Mr. Rappaport was raising, correct? 24 A. That's correct.</p>	<p style="text-align: right;">Page 517</p> <p>1 Q. Did you assist in both the 2 gathering of the information and, 3 ultimately, the -- this presentation that 4 went to the FDA? 5 A. Yes, I did. 6 Q. It starts with a letter that 7 is addressed to Mr. Rappaport 8 specifically, correct? 9 A. That's correct. 10 Q. We reviewed only portions of 11 that letter earlier today during your 12 testimony. 13 But to be clear, it's about 14 a 15-page letter signed by you, correct? 15 A. That's correct. 16 Q. In that letter, you address 17 the concerns raised by the FDA and the 18 requested information; is that right? 19 A. Yes. 20 Q. You provide information with 21 regard to pediatric exposure in the 22 information that the company had 23 compiled; is that right? 24 A. That's correct.</p>

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<p>1 Q. Did you describe, in that 2 letter, details with regard to diversion, 3 abuse and misuse? 4 A. Yes, we did. 5 Q. What is meant by 6 "diversion"? 7 A. Diversion was a product 8 taken or stolen outside of our chain, our 9 supply chain. 10 Q. Did you detail, in this 11 letter, instances that the company was 12 aware of with regard to alleged diversion 13 that had occurred? 14 A. Yes, we did. 15 Q. Alleged abuse? 16 A. Yes, we did. 17 Q. Alleged misuse of the 18 product? 19 A. Yes, we have that 20 information. 21 Q. Overdose information? 22 A. Yes, we have that. 23 Q. Death information? 24 A. Yes.</p>	<p>1 describe certain statistical information 2 that the company had compiled, correct? 3 A. That's correct. 4 Q. Would you categorize -- 5 sorry, would you characterize your letter 6 as open? 7 A. Very much. 8 MR. CRAWFORD: Objection. 9 Vague. 10 BY MR. DIAMANTATOS: 11 Q. How would you characterize 12 your letter, Ms. Marchione, to the FDA? 13 A. Extensive. An extensive 14 summary of the status of misuse, abuse, 15 everything that they were concerned 16 about. 17 Q. Would you call it -- any 18 form of this letter an effort to hide the 19 ball from the FDA? 20 A. Just the contrary. We were 21 completely forthcoming, including our 22 presentations. 23 Q. Is that transparency 24 consistent with all of your</p>
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<p>1 Q. Off-label use? 2 A. Yes. 3 Q. And to be clear -- 4 MR. CRAWFORD: Objection. 5 Form. 6 BY MR. DIAMANTATOS: 7 Q. To be clear, off-label use 8 can include where a prescription, a valid 9 prescription, has been written by a 10 medical professional who may be writing 11 that script off label, correct? 12 A. That's correct. 13 Q. To your knowledge, is there 14 any law or regulation against off-label 15 prescription writing by a medical 16 professional who, in his or her own 17 professional judgment, decides to go off 18 label and write a prescription? 19 A. My understanding, there's no 20 law against that. 21 Q. It's off-label promotion 22 that is not permitted, correct? 23 A. That's correct. 24 Q. The cover letter goes on to</p>	<p>1 communications that you participated in 2 with the FDA during your entire tenure 3 with Cephalon and later Teva? 4 MR. CRAWFORD: Objection to 5 form. 6 THE WITNESS: I believe that 7 it was. 8 BY MR. DIAMANTATOS: 9 Q. I just want to highlight the 10 table of contents, which is found on 11 Bates number 5307. It's immediately 12 after the 15-page letter. 13 A. Yes. 14 Q. Am I correct -- and I don't 15 want to go through each of the 16 attachments, but counsel didn't spend a 17 lot of time on this particular exhibit 18 during his examination. 19 But am I correct that you 20 included a number of items to supplement 21 the letter that you submitted to the FDA 22 in this time frame? 23 A. Yes, we did. 24 Q. Attachments included</p>

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<p style="text-align: right;">Page 522</p> <p>1 correspondence that you had engaged 2 with -- prior to this occasion, with the 3 FDA on this topic?</p> <p>4 A. On the RMP, yes.</p> <p>5 Q. What is an RMP?</p> <p>6 A. The risk management program.</p> <p>7 Q. Okay. You included the risk 8 management program quarterly report, or 9 at least examples of them?</p> <p>10 A. That's correct.</p> <p>11 Q. You included attachments 12 that detailed pediatric exposure summary 13 information and pediatric exposure 14 listing information, correct?</p> <p>15 A. That's correct.</p> <p>16 Q. Diversion summary 17 information?</p> <p>18 A. That's correct.</p> <p>19 Q. Diversion listing?</p> <p>20 A. That's correct.</p> <p>21 Q. Drug abuse summary 22 information?</p> <p>23 A. That's correct.</p> <p>24 Q. Drug abuse listing?</p>	<p style="text-align: right;">Page 524</p> <p>1 included in this presentation the 2 concerns that Mr. Brennan had raised, 3 internally first with the company, and 4 thereafter in the letter that we saw that 5 he sent to the FDA, correct?</p> <p>6 A. That's correct.</p> <p>7 Q. You also included Cephalon's 8 response to that audit report?</p> <p>9 A. Yes, we did.</p> <p>10 Q. Did you ever attempt to hide 11 what Mr. Brennan had raised within the 12 company, as far as the concerns as he 13 perceived them?</p> <p>14 A. No, not at all.</p> <p>15 Q. Did you include Actiq sales 16 training materials as part of your 17 presentation?</p> <p>18 A. Yes, we did.</p> <p>19 Q. It appears as, at least 20 based on the table of contents, that that 21 was a very voluminous portion of the 22 exhibit, correct?</p> <p>23 A. Yes.</p> <p>24 Q. And to be clear, any type of</p>
<p style="text-align: right;">Page 523</p> <p>1 A. That's correct.</p> <p>2 Q. Misuse summary information?</p> <p>3 A. Yes, we did.</p> <p>4 Q. Misuse listing?</p> <p>5 A. Yes, we did.</p> <p>6 Q. Overdose summary 7 information?</p> <p>8 A. Yes, we did.</p> <p>9 Q. Overdose listing?</p> <p>10 A. Yes.</p> <p>11 Q. Fatal outcome summary 12 information?</p> <p>13 A. Yes.</p> <p>14 Q. Fatal outcomes listing --</p> <p>15 A. Yes.</p> <p>16 Q. -- parens, spontaneous, 17 closed parens?</p> <p>18 A. Yes.</p> <p>19 Q. Actiq off-label counts 20 versus patient exposure?</p> <p>21 A. Yes.</p> <p>22 Q. Cephalon RMP audit report?</p> <p>23 A. Yes.</p> <p>24 Q. And to be clear, you</p>	<p style="text-align: right;">Page 525</p> <p>1 marketing material that was to be used by 2 the company needed to be vetted first by 3 you and your team, correct?</p> <p>4 A. Any marketing that was going 5 to be distributed to healthcare 6 providers, yes.</p> <p>7 Q. And that also needed to be 8 submitted to the FDA, correct?</p> <p>9 A. Yes, that's correct.</p> <p>10 Q. And, of course, we heard 11 today about the back-and-forth with 12 regard to the FDA taking issue, 13 potentially, with certain promotional 14 materials and making recommendations on 15 how the materials needed to be changed, 16 right?</p> <p>17 A. Yes, correct.</p> <p>18 Q. And I think you detailed for 19 us that in each and every one of those 20 instances, you and your team took action 21 to correct those materials in line with 22 what the FDA had suggested, right?</p> <p>23 A. Yes, we did.</p> <p>24 Q. To your knowledge, were any</p>

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<p style="text-align: right;">Page 526</p> <p>1 of the materials that you submitted and 2 the FDA ultimately approved, did they 3 describe any type of off-label promoting 4 or marketing?</p> <p>5 A. We never received any 6 feedback from the agency, once we 7 submitted it, the final copies.</p> <p>8 Q. According to the table of 9 contents, you also attached a sales 10 bulletin.</p> <p>11 In this instance, Sales 12 Bulletin Number 9, right?</p> <p>13 A. Yes.</p> <p>14 Q. Example of unbranded 15 promotional piece?</p> <p>16 A. Yes.</p> <p>17 Q. Example of Actiq branded 18 promotional piece?</p> <p>19 A. Yes.</p> <p>20 Q. Actiq journal articles?</p> <p>21 A. Yes.</p> <p>22 Q. Cephalon compliance program?</p> <p>23 A. Yes.</p> <p>24 Q. Regulation of pharmaceutical</p>	<p style="text-align: right;">Page 528</p> <p>1 tenure as regulatory -- in regulatory 2 affairs, in any capacity, did you receive 3 a warning letter from the FDA with regard 4 to Actiq?</p> <p>5 MR. CRAWFORD: Objection. 6 Form.</p> <p>7 THE WITNESS: No.</p> <p>8 BY MR. DIAMANTATOS:</p> <p>9 Q. Same question with regard to 10 Fentora.</p> <p>11 Did you ever receive a 12 warning letter from the FDA with regard 13 to Fentora?</p> <p>14 MR. CRAWFORD: Objection. 15 Form.</p> <p>16 THE WITNESS: No.</p> <p>17 BY MR. DIAMANTATOS:</p> <p>18 Q. Did you ever receive what 19 you referred to earlier as an NOV?</p> <p>20 Do you recall that answer 21 that you gave earlier?</p> <p>22 A. We had one NOV letter. And, 23 I'm sorry, I didn't remember if it was 24 for Treanda --</p>
<p style="text-align: right;">Page 527</p> <p>1 products compliance program?</p> <p>2 A. Yes.</p> <p>3 Q. Business ethics review 4 questionnaire?</p> <p>5 A. Yes.</p> <p>6 Q. Historical overview of Actiq 7 approval and risk management program?</p> <p>8 A. Yes.</p> <p>9 Q. And a number of summaries of 10 certain media coverage having to do with 11 Actiq, correct?</p> <p>12 A. Yes.</p> <p>13 Q. You also included Cephalon 14 initiatives for risk minimization, 15 correct?</p> <p>16 A. That's correct.</p> <p>17 Q. At any point in time, did 18 you receive a warning letter from the FDA 19 with regard to Actiq?</p> <p>20 A. No.</p> <p>21 MR. CRAWFORD: Objection.</p> <p>22 Vague.</p> <p>23 BY MR. DIAMANTATOS:</p> <p>24 Q. At any point in time in your</p>	<p style="text-align: right;">Page 529</p> <p>1 Q. What is an NOV?</p> <p>2 A. A notice of violation, which 3 means not as significant as a warning; 4 the FDA wants you to correct an issue.</p> <p>5 Q. At any point in time, did 6 the FDA pull its approval of Actiq?</p> <p>7 A. No.</p> <p>8 Q. At any point in time, did 9 the FDA pull its approval of Fentora?</p> <p>10 A. No.</p> <p>11 Q. To be clear, we talked about 12 Fentora's approval, and I know counsel 13 went through the timeline for you, and we 14 were able to pinpoint, through a number 15 of documents, including the timeline, 16 that the FDA approved Fentora some time 17 in 2006, correct?</p> <p>18 A. That's correct.</p> <p>19 Q. Was that after this meeting 20 that we talked about in July 12th of 2004 21 where the FDA --</p> <p>22 A. Yes.</p> <p>23 Q. -- had concerns?</p> <p>24 A. Yes, it is.</p>

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<p>1 Q. To be clear, the indication 2 for Actiq was identical to the indication 3 for Fentora, correct? 4 A. That's correct. 5 Q. Did the Fentora approval 6 come after the concerns raised in Mr. 7 Brennan's letter with regard to Actiq? 8 A. Yes, they did. 9 Q. Did they come after the 10 concerns raised by Dr. Rappaport in his 11 phone call to you and in his 12 correspondence to you? 13 A. Yes, it did. 14 Q. Going back to the notion of 15 black box warnings. 16 Counsel covered with you 17 what a black box warning is, and you 18 described that. 19 Am I correct that all of the 20 marketing materials that were used with 21 Actiq and Fentora included that black box 22 warning? 23 A. Yes, it did. 24 Q. Isn't a black box warning a</p>	<p>1 sales individuals. 2 The training that you 3 participated in with sales individuals, 4 what, if anything, did you describe to 5 them needed to be done in terms of their 6 education of doctors that they were 7 visiting? 8 A. So my part of the training 9 was to review the RiskMAP, I went through 10 all the elements, what the FDA was 11 concerned about, how we had to report 12 information, and the specific details. 13 Q. Counsel entered an exhibit 14 and asked you about the 2008 guilty plea 15 that the company entered into. 16 Do you recall that? 17 A. Yes, I do. 18 Q. You mentioned -- in 19 response, you made reference to a CIA. 20 Do you remember that? 21 A. Yes, I do. 22 Q. Were you referring to a 23 corporate integrity agreement? 24 A. Yes, I was.</p>
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<p>1 form of an educational piece? 2 MR. CRAWFORD: Objection. 3 Vague. 4 BY MR. DIAMANTATOS: 5 Q. Let me be clear. 6 Does a black box warning -- 7 the marketing materials, do they need to 8 contain information about the label 9 indication? 10 Is that a yes? 11 A. Yes, it is. 12 Q. Okay. Do they need to 13 contain information about the benefits of 14 a product? 15 A. Yes. But the FDA wants you 16 to put safety first. 17 Q. Safety goes first, right? 18 A. Yes. 19 Q. And every single piece of 20 marketing has to include safety and risk 21 information, right? 22 A. That's correct. 23 Q. You described earlier for us 24 that you participated in training with</p>	<p>1 Q. Am I correct that you were 2 aware that there was a corporate 3 integrity agreement in place, correct? 4 A. Yes, I was. 5 Q. Did you have to sign, 6 acknowledging that you were aware of the 7 corporate integrity agreement and exactly 8 what it spelled out the company needed to 9 do? 10 A. Yes, I did. 11 Q. Do you recall how long of a 12 time period the corporate integrity 13 agreement covered? 14 A. Not -- not -- 15 Q. Was it multiple years? 16 A. It was multiple years. 17 Q. Did you and members of your 18 team follow exactly what the corporate 19 integrity agreement spelled out the 20 company needed to do? 21 A. I can only speak for myself. But yes. 22 Q. To your knowledge, did 23 people on your team also abide by what</p>

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<p style="text-align: right;">Page 534</p> <p>1 the corporate integrity agreement 2 called -- 3 A. To my knowledge. 4 Q. At any point in time after 5 2008 and the guilty plea referenced by 6 counsel, did the FDA pull approval for 7 Fentora? 8 A. No, it did not. 9 Q. It might have not been 10 pertinent at this time, but was Actiq's 11 approval ever pulled? 12 A. No, it was not. 13 Q. There was a description 14 about a TIRF REMS program in the 15 afternoon portion of your testimony. 16 Can you please explain what 17 a TIRF REMS program is? Do you know what 18 the acronym stands for? 19 A. Actually, I don't -- I don't 20 remember. 21 Q. Okay. What is it? What's a 22 TIRF REMS program? 23 A. To my recollection, again, 24 the FDA started requesting manufacturers</p>	<p style="text-align: right;">Page 536</p> <p>1 Q. And that information is 2 gathered and, of course, provided to the 3 FDA, right? 4 A. That was my recollection. 5 Q. And am I correct that all of 6 Teva and Cephalon's opioid medications 7 that we've been discussing today, 8 including Actiq and Fentora, were FDA 9 approved and only available through a 10 prescription? 11 A. Yes. 12 Q. Am I correct that the FDA 13 approved both of these opioid 14 medications, notwithstanding the risks? 15 A. Yes. 16 Q. Am I correct that the 17 prescribing information and patient 18 labels provide information regarding 19 risks and benefits of the prescription 20 opioid? 21 A. Yes. 22 Q. Including the black box 23 warning that counsel walked you through 24 earlier this afternoon?</p>
<p style="text-align: right;">Page 535</p> <p>1 of short-acting, long-acting programs to 2 discuss, in groups, what the requirements 3 were in order to have consistency and not 4 to have extreme redundancy then be 5 imposed upon physicians, in terms of -- 6 in terms of impacting the areas of 7 distribution and the whole chain of the 8 product. 9 Q. You mentioned "chain of the 10 product." 11 Am I correct that only 12 certain doctors are authorized to write 13 scripts for products that fall within the 14 TIRF's category? 15 A. I believe having a 16 controlled product limits the prescribing 17 of who can -- what levels can prescribe. 18 Q. How about patients; patients 19 need to sign up for the TIRF REMS program 20 as well, don't they? 21 A. My recollection, that was 22 what they were trying to initiate, yes. 23 Q. Distributors? 24 A. Yes.</p>	<p style="text-align: right;">Page 537</p> <p>1 A. Yes. 2 Q. And that black box warning 3 includes information about risk of 4 addiction, correct? 5 A. That's correct. 6 MR. DIAMANTATOS: I don't 7 have any further questions for the 8 witness. Thank you, Ms. 9 Marchione. 10 THE WITNESS: Thank you. 11 MR. CRAWFORD: I have a 12 couple. 13 How many minutes do I have? 14 VIDEO TECHNICIAN: Nineteen. 15 - - - 16 EXAMINATION 17 - - - 18 BY MR. CRAWFORD: 19 Q. Counsel asked you about a 20 corporate integrity agreement that was 21 entered into by the company with the U.S. 22 government, right? 23 A. Correct. 24 Q. Is it your understanding</p>

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<p>1 that that was a -- what's your 2 understanding of why they were required 3 to enter into a corporate integrity 4 agreement?</p> <p>5 MR. DIAMANTATOS: Objection. 6 Form. Calls for a legal 7 conclusion. Foundation.</p> <p>8 THE WITNESS: My 9 recollection, reading and signing 10 it, is that there were violations 11 of marketing and that the DOJ, I 12 think, or -- I mean, the Justice 13 Department or -- I can't remember 14 the exact details -- but wanted to 15 have oversight of the company for 16 corrective action.</p> <p>17 BY MR. CRAWFORD: 18 Q. And corrective action 19 because, previously, the government had 20 found that the company was marketing 21 products off label, correct?</p> <p>22 MR. DIAMANTATOS: Objection. 23 Form. Foundation.</p> <p>24 THE WITNESS: Going back to</p>	<p>1 Form. 2 THE WITNESS: The RiskMAP 3 was to support the 4 commercialization of the product 5 in a safe way, yes.</p> <p>6 BY MR. CRAWFORD: 7 Q. And they were integral to 8 the approval, were the words of the FDA, 9 right?</p> <p>10 A. Yes, that's correct. 11 Q. And you're aware -- strike 12 that.</p> <p>13 If you could pick up 14 Exhibit-11. This was the July 12th, 2004 15 submission that you had made to the FDA 16 prior to the July 14th meeting that 17 counsel asked you about just now, 18 correct?</p> <p>19 A. Yes. 20 Q. And this is information that 21 the FDA specifically requested be 22 provided to it before the meeting, 23 correct?</p> <p>24 A. Yes.</p>
<p>1 the document you showed me, that 2 appeared to be the case, yes.</p> <p>3 BY MR. CRAWFORD: 4 Q. And it included Actiq, 5 off-label promotion of Actiq, correct?</p> <p>6 MR. DIAMANTATOS: Same 7 objections.</p> <p>8 THE WITNESS: That's what it 9 said in that document, yes.</p> <p>10 BY MR. CRAWFORD: 11 Q. And counsel had asked you 12 about doctors being able to prescribe off 13 label, prescribe products off label.</p> <p>14 But a company -- a 15 pharmaceutical company is not allowed to 16 promote a drug off label, in other words, 17 for nonindicated uses, correct?</p> <p>18 A. That's correct.</p> <p>19 Q. And, in fact, when the FDA 20 approved Actiq and Fentora, it approved 21 it on a condition that the RiskMAPs be 22 adhered to, to ensure that the drugs be 23 used safely, right?</p> <p>24 MR. DIAMANTATOS: Objection.</p>	<p>1 But I'd have to look at, did 2 we add anything additional? I just don't 3 remember if we had additional information 4 in this.</p> <p>5 Q. But much of it was actually 6 requested by the FDA?</p> <p>7 A. Yes.</p> <p>8 Q. And then, in fact, when the 9 information was given to the FDA, they 10 and DDMAC expressed great alarm over what 11 they were seeing in your packet that you 12 gave, right?</p> <p>13 MR. DIAMANTATOS: Objection. 14 Form. Vague.</p> <p>15 THE WITNESS: So we had two 16 meetings. The initial meeting, 17 which -- where DDMAC was part 18 of -- actually, there were 19 approximately 60, 70 people from 20 FDA in the room. There was no -- 21 there was no negative feedback 22 during that discussion, and they 23 thanked us for coming.</p> <p>24 The secondary meeting with</p>

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<p>1 DDMAC, who, in their meeting 2 minutes, showed concern about 3 the -- we went through the 4 information. They expressed their 5 concerns about some of the 6 marketing targets.</p> <p>7 BY MR. CRAWFORD:</p> <p>8 Q. Right. So this packet, 9 which is, you know, at least a couple of 10 inches thick, was submitted two days 11 prior to the meeting, right?</p> <p>12 A. Oh, God, I'd have to -- I'd 13 have to check. I don't know.</p> <p>14 Q. The meeting was July 14th, 15 right? That's what it references --</p> <p>16 A. Okay. And so the 17 submission --</p> <p>18 Q. -- on the letter, right?</p> <p>19 A. Submission date was the 20 12th, that's correct.</p> <p>21 Q. And it references a July 22 14th meeting, right?</p> <p>23 A. That's correct.</p> <p>24 Q. You said there were 60</p>	<p>1 Form. 2 Go ahead.</p> <p>3 THE WITNESS: During the 4 meeting, they -- I mean, there 5 were questions. But it was -- it 6 was very -- it was really 7 one-sided where we presented 8 everything. And then we got the 9 meeting minutes that reviewed it.</p> <p>10 But during that meeting, 11 they asked questions, there were 12 concerns. But they didn't -- they 13 didn't, at the end of it, say, 14 we're really -- a lot of issues or 15 problems.</p> <p>16 We did hear that at the 17 DDMAC meeting. So that was where 18 it was more expressed.</p> <p>19 BY MR. CRAWFORD:</p> <p>20 Q. Right. The DDMAC was very 21 concerned about these materials you had 22 submitted, correct?</p> <p>23 MR. DIAMANTATOS: Objection. 24 Form. Calls for speculation.</p>
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<p>1 people from the FDA at the meeting?</p> <p>2 A. Yeah, approximately.</p> <p>3 Q. And then you went through 4 the meeting minutes, and those minutes 5 accurately reflected what happened at the 6 meeting, right?</p> <p>7 MR. DIAMANTATOS: Objection 8 to form. Mischaracterizes the 9 witness's testimony.</p> <p>10 THE WITNESS: Right. There 11 were two -- there were two 12 different meeting minutes.</p> <p>13 BY MR. CRAWFORD:</p> <p>14 Q. Meaning the July 14th 15 minutes --</p> <p>16 A. Yes, yes.</p> <p>17 Q. -- that the FDA provided?</p> <p>18 A. Yes.</p> <p>19 Q. Those were accurate?</p> <p>20 A. I believe so.</p> <p>21 Q. And the FDA did express a 22 number of concerns about the off-label 23 marketing in that meeting, correct?</p> <p>24 MR. DIAMANTATOS: Objection.</p>	<p>1 THE WITNESS: We reviewed 2 those. So however they -- I mean, 3 that's the -- that's how you -- 4 they were concerned about the 5 issues, yes.</p> <p>6 BY MR. CRAWFORD:</p> <p>7 Q. So if you pull up 8 Exhibit-22, these concerns were 9 expressed --</p> <p>10 A. I believe they were.</p> <p>11 Q. -- at length in these 12 minutes that were provided at the 13 meeting, correct? If you can pull that 14 up.</p> <p>15 A. Is it the DDMAC one?</p> <p>16 Q. Right.</p> <p>17 A. Yes.</p> <p>18 Q. If you can pull those out 19 and look at the second -- second page at 20 the top.</p> <p>21 A. The one doesn't seem to have 22 a label, by the way.</p> <p>23 Q. It doesn't?</p> <p>24 A. It may be his copy, I don't</p>

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<p style="text-align: right;">Page 546</p> <p>1 know.</p> <p>2 Q. We'll have to check that,</p> <p>3 then.</p> <p>4 It says, DDMAC agreed to</p> <p>5 meet with Cephalon and also stated that</p> <p>6 it would like to discuss various concerns</p> <p>7 DDMAC had regarding the promotion of</p> <p>8 Actiq, including concerns regarding</p> <p>9 information about Cephalon's promotion</p> <p>10 that was provided by Cephalon during the</p> <p>11 July 14th, 2004 joint division meeting</p> <p>12 and in Cephalon's briefing package for</p> <p>13 the July 14th, 2004 meeting.</p> <p>14 They are referencing the --</p> <p>15 the July 12th submission was the briefing</p> <p>16 package you provided, right?</p> <p>17 A. That's correct.</p> <p>18 Q. And so once they had a</p> <p>19 chance to look through that, they were</p> <p>20 meeting with you here to express their</p> <p>21 concerns about what you provided them in</p> <p>22 the packet?</p> <p>23 MR. DIAMANTATOS: Objection.</p> <p>24 Form. Foundation. Calls for</p>	<p style="text-align: right;">Page 548</p> <p>1 yes.</p> <p>2 MR. DIAMANTATOS: Objection.</p> <p>3 Form. Foundation. Calls for</p> <p>4 speculation. Asked and answered.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. All right.</p> <p>7 MR. CRAWFORD: But I'm just</p> <p>8 following up on your questions</p> <p>9 here.</p> <p>10 BY MR. CRAWFORD:</p> <p>11 Q. On 3, DDMAC did express</p> <p>12 concerns about the briefing package and</p> <p>13 its presentation instructing sales</p> <p>14 force -- its sales force to open sales</p> <p>15 calls in a manner that fails to focus on</p> <p>16 Actiq's limited indication and instead</p> <p>17 focuses on the physician's treatment of</p> <p>18 breakthrough pain in general, thus,</p> <p>19 inappropriately broadening physician's</p> <p>20 perceptions of the drug's use to treat --</p> <p>21 the treatment of all forms of BTP, rather</p> <p>22 than BTCP in the indicated population,</p> <p>23 correct?</p> <p>24 MR. DIAMANTATOS: Objection.</p>
<p style="text-align: right;">Page 547</p> <p>1 speculation. Asked and answered.</p> <p>2 THE WITNESS: This is a</p> <p>3 subsection of FDA, this is the</p> <p>4 promotion review section.</p> <p>5 BY MR. CRAWFORD:</p> <p>6 Q. All right. So on Number 2,</p> <p>7 that first sentence there saying that,</p> <p>8 DDMAC expressed concerns that, as</p> <p>9 indicated by Cephalon's briefing package</p> <p>10 for and presentation at the July 14th,</p> <p>11 2004 meeting, the company targets</p> <p>12 physicians for Actiq promotion purely</p> <p>13 based on the number of opioid</p> <p>14 prescriptions they write, and the company</p> <p>15 is making no effort to screen these</p> <p>16 targeted physicians to determine whether</p> <p>17 they treat cancer patients and, thus,</p> <p>18 would be appropriate to be detailed on</p> <p>19 Actiq, given its limited indication.</p> <p>20 So the briefing packet and</p> <p>21 the presentation actually raised a</p> <p>22 serious concern by DDMAC, would you</p> <p>23 agree, about the targeting of physicians?</p> <p>24 A. That's what it says here,</p>	<p style="text-align: right;">Page 549</p> <p>1 Form. Foundation. Calls for</p> <p>2 speculation. Document speaks for</p> <p>3 itself. Asked and answered.</p> <p>4 THE WITNESS: That's what it</p> <p>5 says here.</p> <p>6 And there's also a response</p> <p>7 from Cephalon that says that we</p> <p>8 trained our sales representatives</p> <p>9 to always provide the label</p> <p>10 indication for Actiq during its</p> <p>11 sales calls and promote only</p> <p>12 Actiq's labeled education. It</p> <p>13 educates them on therapeutic area,</p> <p>14 pain in general.</p> <p>15 BY MR. CRAWFORD:</p> <p>16 Q. We'll go into -- directly to</p> <p>17 4 and 5. Again, you agree with me that</p> <p>18 DDMAC is expressing concerns about</p> <p>19 information Cephalon has provided in the</p> <p>20 briefing package, right?</p> <p>21 MR. DIAMANTATOS: Objection.</p> <p>22 Form. Foundation. Asked and</p> <p>23 answered.</p> <p>24 THE WITNESS: Yes.</p>

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<p style="text-align: right;">Page 550</p> <p>1 BY MR. CRAWFORD:</p> <p>2 Q. So in sum, the FDA had</p> <p>3 requested much of the information, you</p> <p>4 would agree, in the briefing package.</p> <p>5 And then when they had time</p> <p>6 to look at it, and they had that meeting,</p> <p>7 DDMAC, on August 30th, they expressed a</p> <p>8 number of concerns about what they were</p> <p>9 seeing in that package, right?</p> <p>10 MR. DIAMANTATOS: Same</p> <p>11 objections.</p> <p>12 THE WITNESS: That's what it</p> <p>13 says here, yes.</p> <p>14 MR. CRAWFORD: That's all I</p> <p>15 have. Thank you.</p> <p>16 - - -</p> <p>17 (Whereupon, Teva-Marchione</p> <p>18 Exhibit-39, TEVA_MDL_A_074679522,</p> <p>19 was marked for identification.)</p> <p>20 - - -</p> <p>21 VIDEO TECHNICIAN: This ends</p> <p>22 today's deposition. We're going</p> <p>23 off the record. The time is 6:43</p> <p>24 p.m.</p>	<p style="text-align: right;">Page 552</p> <p>1 CERTIFICATE</p> <p>2</p> <p>3</p> <p>4 I HEREBY CERTIFY that the</p> <p>5 witness was duly sworn by me and that the</p> <p>6 deposition is a true record of the</p> <p>7 testimony given by the witness.</p> <p>8</p> <p>9</p> <p>10</p> <p>11 Amanda Maslynsky-Miller Certified Realtime Reporter Dated: January 21, 2019</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17 (The foregoing certification 18 of this transcript does not apply to any 19 reproduction of the same by any means, 20 unless under the direct control and/or 21 supervision of the certifying reporter.)</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 551</p> <p>1 - - -</p> <p>2 (Whereupon, the deposition</p> <p>3 concluded at 6:43 p.m.)</p> <p>4 - - -</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 553</p> <p>1 INSTRUCTIONS TO WITNESS</p> <p>2</p> <p>3 Please read your deposition</p> <p>4 over carefully and make any necessary</p> <p>5 corrections. You should state the reason</p> <p>6 in the appropriate space on the errata</p> <p>7 sheet for any corrections that are made.</p> <p>8 After doing so, please sign</p> <p>9 the errata sheet and date it.</p> <p>10 You are signing same subject</p> <p>11 to the changes you have noted on the</p> <p>12 errata sheet, which will be attached to</p> <p>13 your deposition.</p> <p>14 It is imperative that you</p> <p>15 return the original errata sheet to the</p> <p>16 deposing attorney within thirty (30) days</p> <p>17 of receipt of the deposition transcript</p> <p>18 by you. If you fail to do so, the</p> <p>19 deposition transcript may be deemed to be</p> <p>20 accurate and may be used in court.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p style="text-align: center;">Page 554</p> <p>1 ----- 2 ----- 3 ER R A T A 4 ----- 5 PAGE LINE CHANGE/REASON 6 ----- 7 ----- 8 ----- 9 ----- 10 ----- 11 ----- 12 ----- 13 ----- 14 ----- 15 ----- 16 ----- 17 ----- 18 ----- 19 ----- 20 ----- 21 ----- 22 ----- 23 ----- 24 -----</p>	<p style="text-align: center;">Page 556</p> <p>1 LAWYER'S NOTES 2 PAGE LINE 3 ----- 4 ----- 5 ----- 6 ----- 7 ----- 8 ----- 9 ----- 10 ----- 11 ----- 12 ----- 13 ----- 14 ----- 15 ----- 16 ----- 17 ----- 18 ----- 19 ----- 20 ----- 21 ----- 22 ----- 23 ----- 24 -----</p>
<p style="margin-top: 10px;">Page 555</p> <p>1 ACKNOWLEDGMENT OF DEPONENT 2 3 I, _____, do 4 hereby certify that I have read the 5 foregoing pages, 1 - 551, and that the 6 same is a correct transcription of the 7 answers given by me to the questions 8 therein propounded, except for the 9 corrections or changes in form or 10 substance, if any, noted in the attached 11 Errata Sheet.</p> <p>12 _____</p> <p>13 CAROL MARCHIONE DATE</p> <p>14 Subscribed and sworn 15 to before me this 16 _____ day of _____, 20_____. 17 My commission expires: _____</p> <p>18 Notary Public</p> <p>19 20 21 22 23 24</p>	

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